eIRB User Manual

Research Subjects Protections Office
Kaiser Permanente Northwest

CONTACT INFORMATION

eIRB Technical Support: 503-528-3945 (tieline 60 3945)

Email: eIRB@kpchr.org

Mail:

Kaiser Permanente Center for Health Research
Research Subjects Protections Office
3800 N Interstate Ave.
Portland, OR 97227

RSPO Director:

David Holt, JD, CIP
503-335-6791
David.Holt@kpchr.org

RSPO Administrator:

Sandy Heintz, CIP
503-335-6712
Sandy.Heintz@kpchr.org

IRB Coordinator:

Lisa LaForge
503-335-6699
Lisa.M.LaForge@kpchr.org

RSPO Technician:

David Matthews
503-335-6357
David.M.Matthews@kpchr.org

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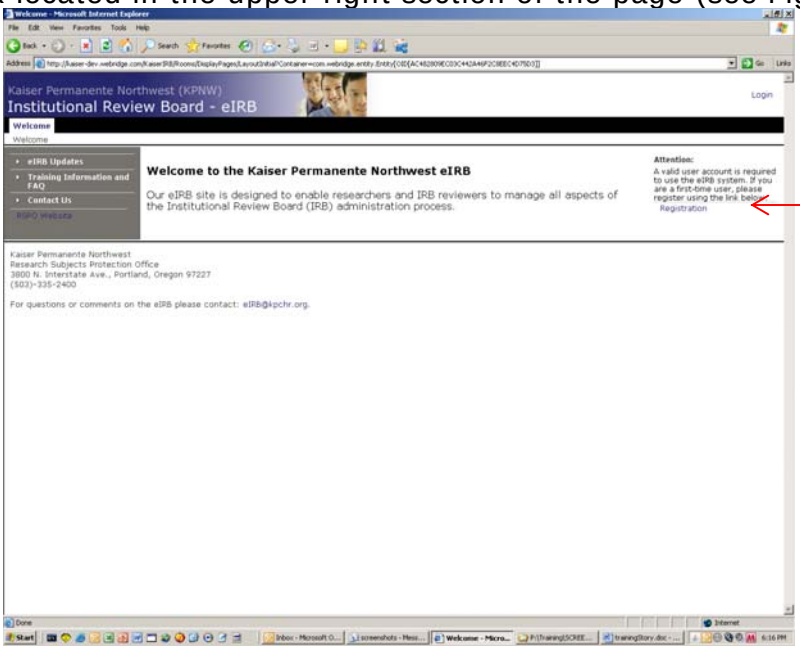
INTRODUCTION

The Electronic Institutional Review Board, from here on referred to as the eIRB, is a web-based application that provides tools for submitting and managing requests to the KPNW IRB for approval of human subjects research. The electronic system streamlines the process of submitting research studies through the IRB by eliminating the need for most paper, and providing an easy way to process all study-related documentation electronically.

REGISTRATION

To register in the system, open your Internet browser. Go to http://eirb.kpchr.org. Click the "Registration" link located in the upper right section of the page (see Figure 1).


Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Login
Welcome
eIRB Updates
Training Information and FAQ
Contact Us
Welcome to the Kaiser Permanente Northwest eIRB
Our eIRB site is designed to enable researchers and IRB reviewers to manage all aspects of the Institutional Review Board (IRB) administration process.
Attention:
A valid user account is required to use the eIRB system. If you are a first-time user, please register using the link below.
Registration
Kaiser Permanente Northwest
Research Subjects Protection Office
3800 N. Interstate Ave., Portland, Oregon 97227
(503)-335-2400
For questions or comments on the eIRB please contact: eIRB@kpchr.org

You will register once.

Register by clicking here.

Figure 1

Next, fill out and submit the registration form (see Figure 2).

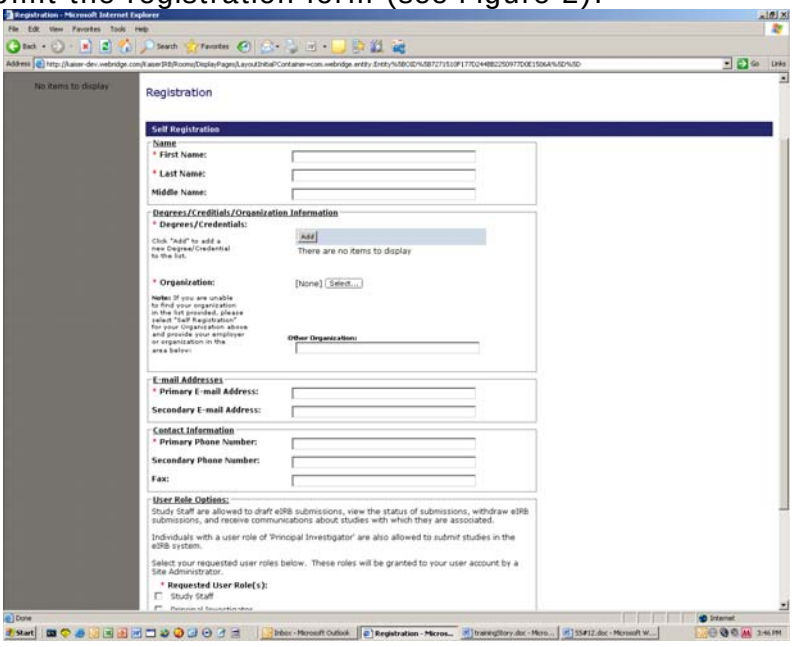
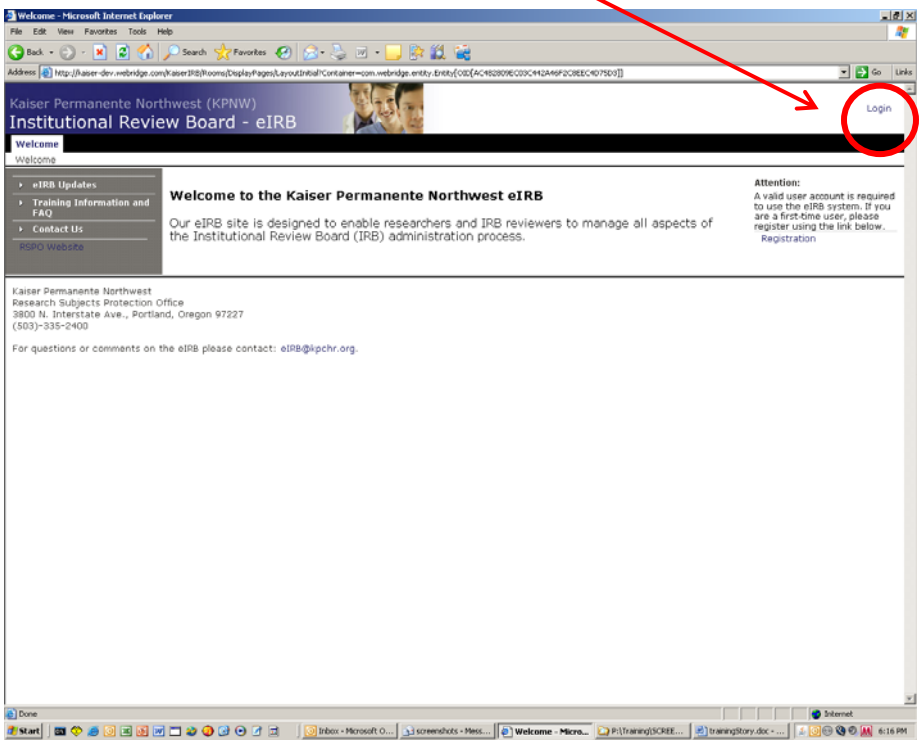


Figure 2

LOGGING INTO THE eIRB

Approximately two business days after submitting the registration form, you will receive an e-mail containing your username and temporary password. You can use this username and temporary password to log into the eIRB. Go to http://eirb.kpchr.org, click on "Login" located in the upper right section of the page, and enter your username and temporary password (see Figure 3).


Welcome - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Login
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Training Information and FAQ
Contact Us
RSPO Website
Welcome to the Kaiser Permanente Northwest eIRB
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Research Subjects Protection Office
3800 N. Interstate Ave., Portland, Oregon 97227
(503)-335-2400
For questions or comments on the eIRB please contact: eIRB@kpchr.org.

Figure 3

After clicking "log-in", enter your username and password (see Figure 4 below). If this is your first time logging in, the eIRB will prompt you to change your password. This is necessary for security reasons. Please safeguard your password. You should be the only person who has access to your eIRB account. Please note that willingly providing your username and password to anyone will constitute a violation of KPNW and CHR policies regarding the use of electronic resources. These policies can be found at the following links:

http://centernet/centernet/LeadershipPolicies/policies/COMP_ACC.html

http://internal.or.kp.org/ice/policies_procedures/2007%20Dec%20HIPAA%20Information%20Security%20Policies/ISP-005ElectronicAccessControl012307.pdf

Disciplinary action —up to and including termination—may be taken against those who fail to adhere to this policy, per KPNW Principles of Responsibility:

http://kpnet.kp.org/national/compliance/principles/introduction_disciplinary.html

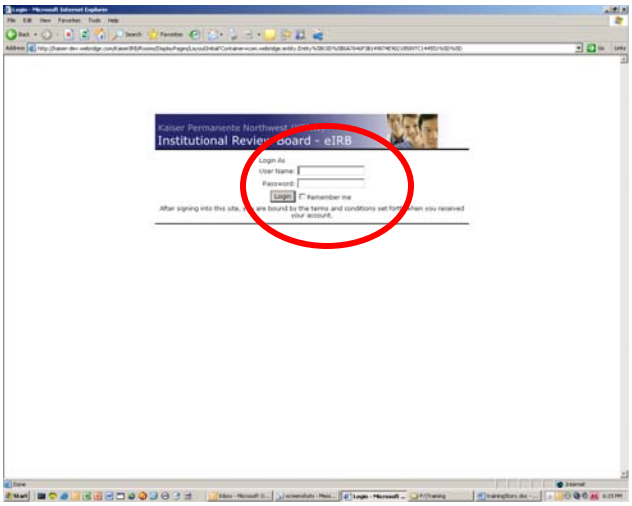


Figure 4

"My Home" Overview

The "My Home" area of the eIRB is considered the starting point of the eIRB system. If you lose track of where you are in the eIRB, you can click on the link "My Home" located in the upper right section of the eIRB system to return to this page (see Figure 5).

In the main area of the "My Home" screen you will find a tab labeled "Inbox" (see Figure 5), which contains the following submission header types: Study Protocols (IRQs/studies), Modifications, Continuing Reviews, and Reportable Events. If the item is listed below one of these headers when the "inbox" tab is selected, some type of action is required from the investigator such as revising the submission as instructed by an IRB staff member, responding to contingencies, etc.

Next to the "My Inbox" tab you will find tabs for the following submission types: Study Protocols (IRQs/studies), Modifications, Continuing Reviews, Reportable Events, Completed/withdrawn studies, and IRB inquiries (see Figure 6). Each tab contains the same type of submissions as described by its name. However, unlike those filtered under the "My Inbox" tab, these tabs contain items that do not, generally, require your action to move them to the next state in the review process.

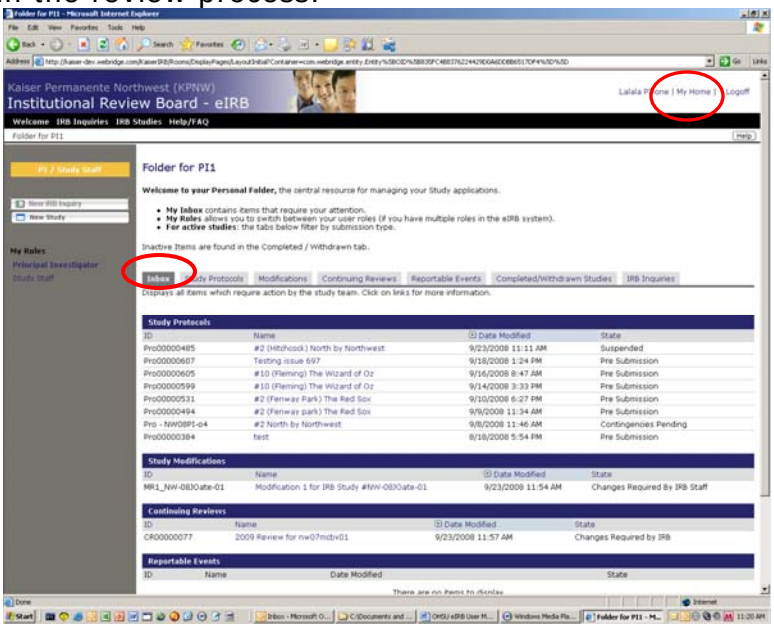

Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Welcome
IRB Inquiries
IRB Studies
Help/FAQ
Folder for PI1
Folder for PI1
Welcome to your Personal Folder, the central resource for managing your Study applications.
My Inbox contains items that require your attention.
My Roles allows you to switch between your user roles (if you have multiple roles in the eIRB system).
For active studies: the tabs below filter by submission type.
Inactive Items are found in the Completed / Withdrawn tab.
Inbox
Study Protocols
Modifications
Continuing Reviews
Reportable Events
Completed/Withdrawn Studies
IRB Inquiries
Displays all items which require action by the study team. Click on links for more information.
Study Protocols
Study Modifications
Continuing Reviews
Reportable Events

Figure 5

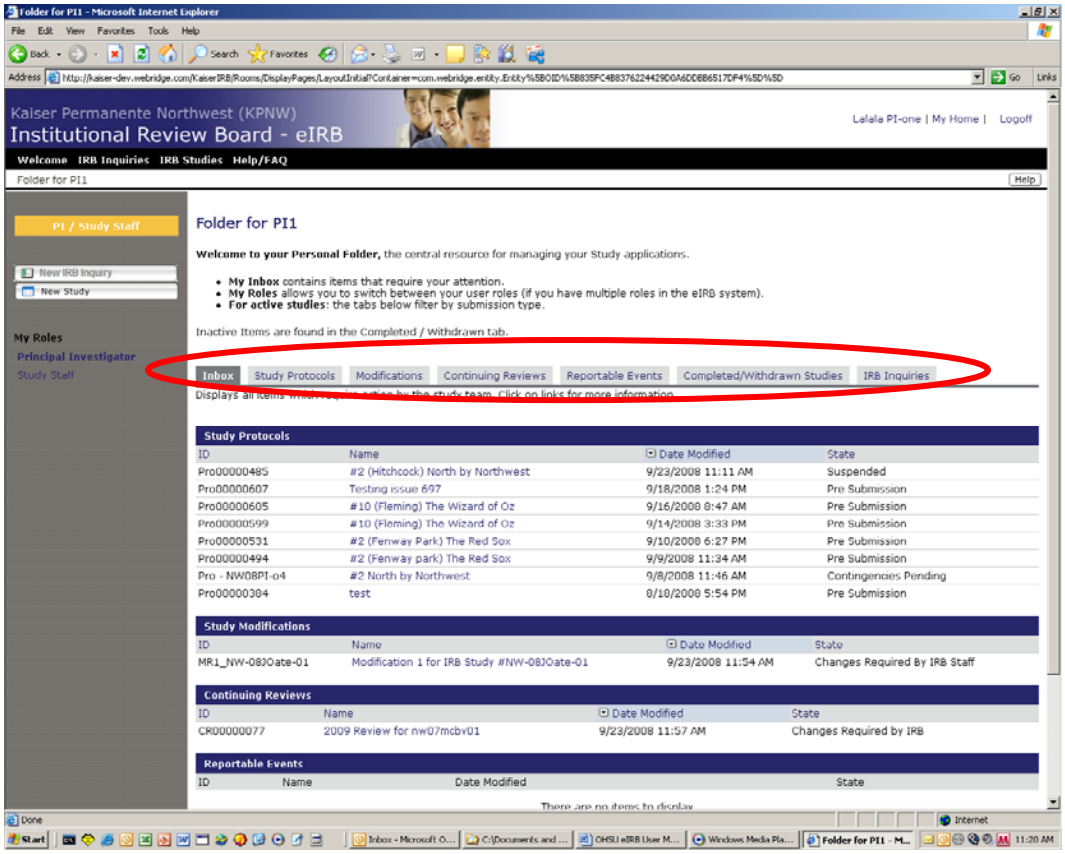

Folder for PI1 - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Lalala PI-one | My Home | Logoff
Welcome IRB Inquiries IRB Studies Help/FAQ
Folder for PI1
PI / Study Staff
New IRB Inquiry
New Study
My Roles
Principal Investigator
Study Staff
Folder for PI1
Welcome to your Personal Folder, the central resource for managing your Study applications.
My Inbox contains items that require your attention.
My Roles allows you to switch between your user roles (if you have multiple roles in the eIRB system).
For active studies: the tabs below filter by submission type.
Inactive Items are found in the Completed / Withdrawn tab.
Inbox
Study Protocols
Modifications
Continuing Reviews
Reportable Events
Completed/Withdrawn Studies
IRB Inquiries
Study Protocols
ID Name Date Modified State
Pro00000485 #2 (Hitchcock) North by Northwest 9/23/2008 11:11 AM Suspended
Pro00000607 Testing issue 697 9/18/2008 1:24 PM Pre Submission
Pro00000605 #10 (Fleming) The Wizard of Oz 9/16/2008 8:47 AM Pre Submission
Pro00000599 #10 (Fleming) The Wizard of Oz 9/14/2008 3:33 PM Pre Submission
Pro00000531 #2 (Fenway Park) The Red Sox 9/10/2008 6:27 PM Pre Submission
Pro00000494 #2 (Fenway park) The Red Sox 9/9/2008 11:34 AM Pre Submission
Pro - NW08PI-04 #2 North by Northwest 9/8/2008 11:46 AM Contingencies Pending
Pro00000384 test 9/10/2008 5:54 PM Pre Submission
Study Modifications
ID Name Date Modified State
MR1_NW-08JOate-01 Modification 1 for IRB Study #NW-08JOate-01 9/23/2008 11:54 AM Changes Required By IRB Staff
Continuing Reviews
ID Name Date Modified State
CR00000077 2009 Review for nw07mcbv01 9/23/2008 11:57 AM Changes Required by IRB
Reportable Events
ID Name Date Modified State
There are no items to display
Done
Internet
Start
11:20 AM

Figure 6

In the left hand section of the "My Home" area you will find 'My roles' (see above, Figure 6), which indicates your role(s) within the eIRB system. Most users will have one of the following:

- Study staff: If you draft/prepare submissions for an investigator but do not act as an investigator, this will be your role.

- Study staff and Principal Investigator (PI): If you draft/prepare submissions and act as an investigator ('Submit' studies on which you are the PI), this will be your role set.

- Study staff, Principal Investigator, and Mentor: If you draft/prepare submissions, act as an investigator ('Submit' studies on which you are the PI), and have the ability to act as a mentor to less experienced researchers, this will be your role set.

If you have multiple roles, click on/ use the role appropriate to your current purpose. The display for your inbox, for example, may differ depending on the role you are using.

Note: From your My Home page, you may click 'Welcome' to see a general, non-tailored eIRB page containing useful contact information for support personnel and materials related to the eIRB system (see below, Figure 7).

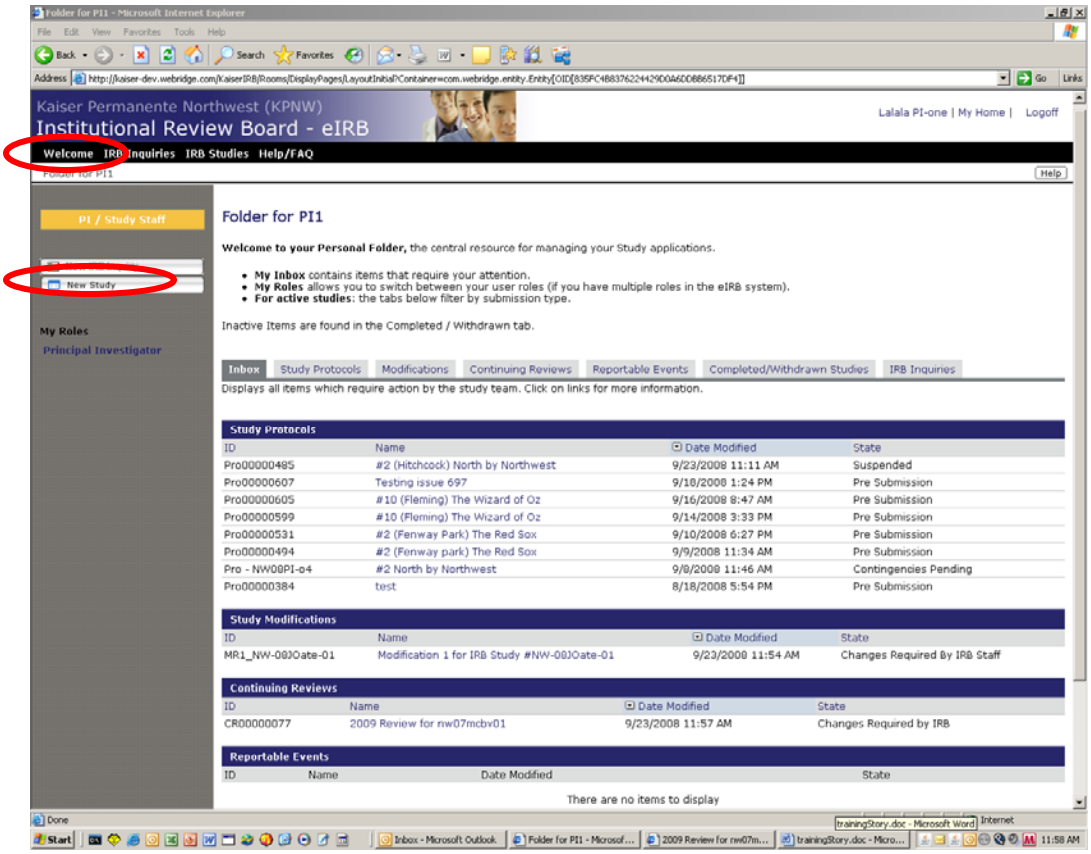


Figure 7

CREATING A NEW STUDY

From the "My Home" environment, on the left hand side of the screen, you have the option to create a 'New Study (see above, Figure 7). This button allows you to access the form through which you can: 1) Submit a request to the IRB to have a new study approved; 2) Convert an existing hardcopy study to the eIRB; or 3) Request that the KPNW IRB cede their review to another IRB for a *new* (not yet submitted) study.

- When you click this 'New Study' button the first page of the Initial Review Questionnaire (IRQ) appears (see Figure 8). Answer the applicable questions on the page. Required fields are indicted by a red asterisk.

- Once you have completed entering information into this first screen, click on the "Continue" button located in the upper and the lower right portion of the page. Alternatively, if you wish to exit and not move beyond the first screen, click on the "Save" link first, which is located in the upper middle portion of the page, and the eIRB system will automatically save your IRQ and create a new IRB number for your study. Once you click "Save" you may click "Exit" to exit the form.

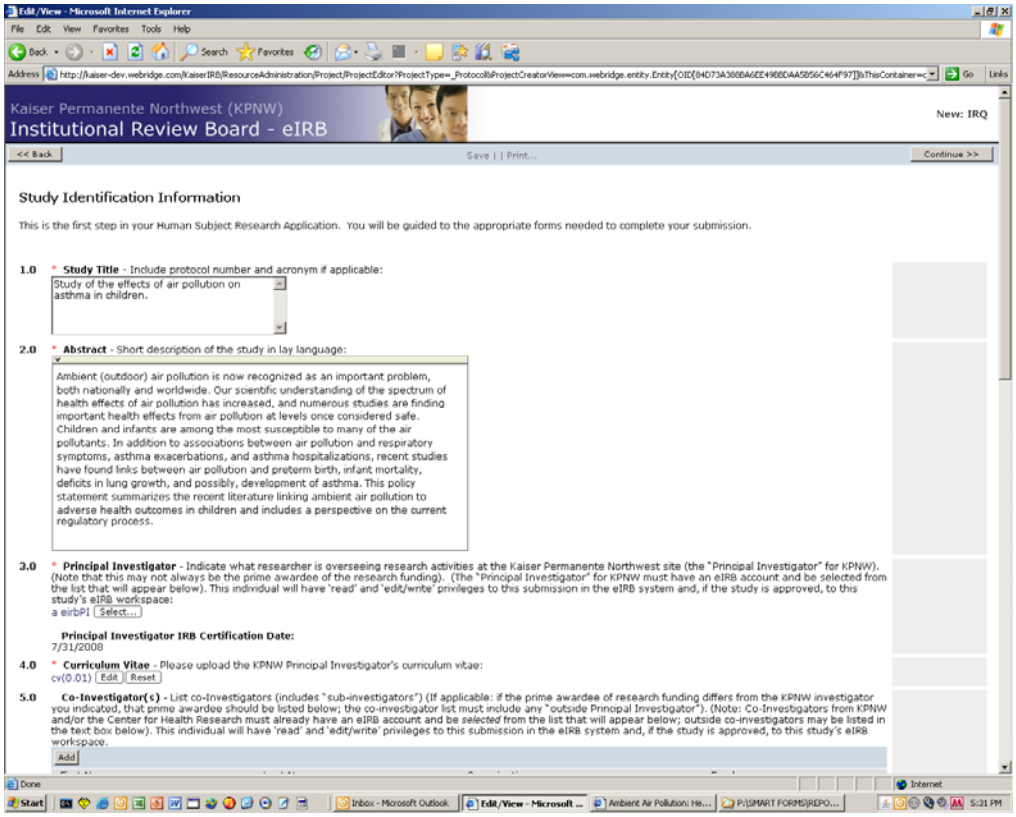

Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
New: IRQ
<< Back
Save | | Print...
Continue >>
Study Identification Information
This is the first step in your Human Subject Research Application. You will be guided to the appropriate forms needed to complete your submission.
1.0 * Study Title - Include protocol number and acronym if applicable:
Study of the effects of air pollution on asthma in children.
2.0 * Abstract - Short description of the study in lay language:
Ambient (outdoor) air pollution is now recognized as an important problem, both nationally and worldwide. Our scientific understanding of the spectrum of health effects of air pollution has increased, and numerous studies are finding important health effects from air pollution at levels once considered safe. Children and infants are among the most susceptible to many of the air pollutants. In addition to associations between air pollution and respiratory symptoms, asthma exacerbations, and asthma hospitalizations, recent studies have found links between air pollution and preterm birth, infant mortality, deficits in lung growth, and possibly, development of asthma. This policy statement summarizes the recent literature linking ambient air pollution to adverse health outcomes in children and includes a perspective on the current regulatory process.
3.0 * Principal Investigator - Indicate what researcher is overseeing research activities at the Kaiser Permanente Northwest site (the "Principal Investigator" for KPNW). (Note that this may not always be the prime awardee of the research funding). (The "Principal Investigator" for KPNW must have an eIRB account and be selected from the list that will appear below). This individual will have 'read' and 'edit/write' privileges to this submission in the eIRB system and, if the study is approved, to this study's eIRB workspace:
a eirbPI Select...
Principal Investigator IRB Certification Date:
7/31/2008
4.0 * Curriculum Vitae - Please upload the KPNW Principal Investigator's curriculum vitae:
cv(0.01) Edit Reset
5.0 Co-Investigator(s) - List co-Investigators (includes "sub-investigators") (If applicable: if the prime awardee of research funding differs from the KPNW investigator you indicated, that prime awardee should be listed below; the co-investigator list must include any "outside Principal Investigator"). (Note: Co-Investigators from KPNW and/or the Center for Health Research must already have an eIRB account and be selected from the list that will appear below; outside co-investigators may be listed in the text box below). This individual will have 'read' and 'edit/write' privileges to this submission in the eIRB system and, if the study is approved, to this study's eIRB workspace.
Add
Done
Internet
Start
Inbox - Microsoft Outlook
Edit/View - Microsoft ...
Ambient Air Pollution: He...
P:\SMART FORMS\REPO...
5:31 PM

Figure 8

Adding Investigators and staff to the study submission

Once the "Select" page has opened, in the "Filter by" drop-down list box, select Last name, First name, or Organization, and enter the search criteria; for example, choose 'Last' name and then enter the first letter of the individual's last name. Click the "Go" button and the name should appear in the results field. Then, select the checkbox next to the person you wish to add, and click "OK" (see Figure 9).

If *you* are/will be drafting the submission, it is very important to add your name to the IRQ in the role of the PI, co-Investigator, primary contact, or other study staff on this first screen. This gives you 'rights' to draft and view this form. **You must add yourself before saving or exiting the IRQ or you will not be able to get back in to the draft submission the next time you log in**. If you do not add yourself before you click Continue, you will receive an error message. If you plan to have no role on the study, you can remove yourself once your drafting work is complete and prior to the investigator 'submitting' to the IRB (see Figure 10).

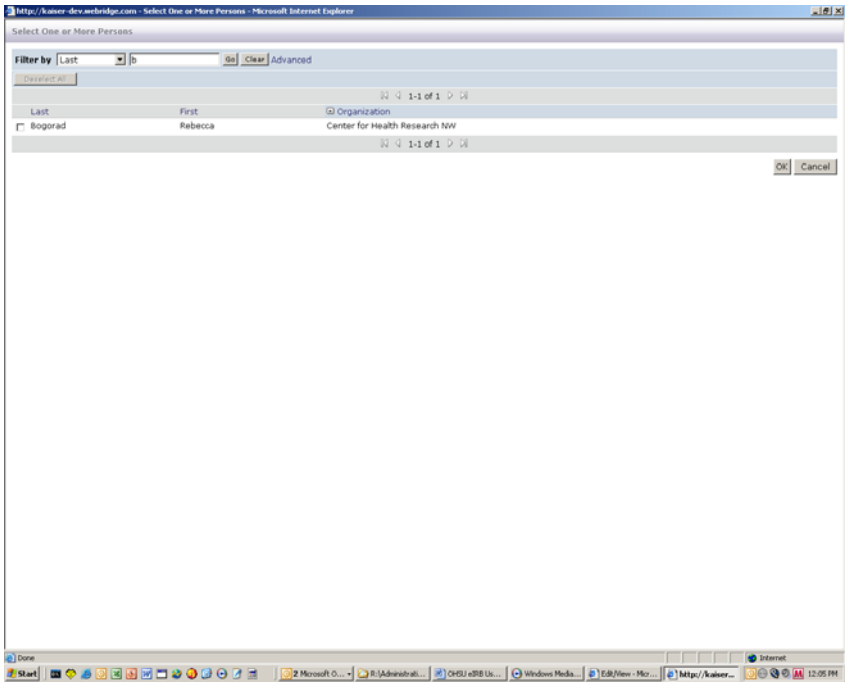


Figure 9

The personnel listed as PI or study staff will receive notifications about submissions as the review process progresses. These notifications contain working links to the submission workspace. Read the notifications carefully as *some are merely informative* and do NOT require any action from the study (see Figure 9a).

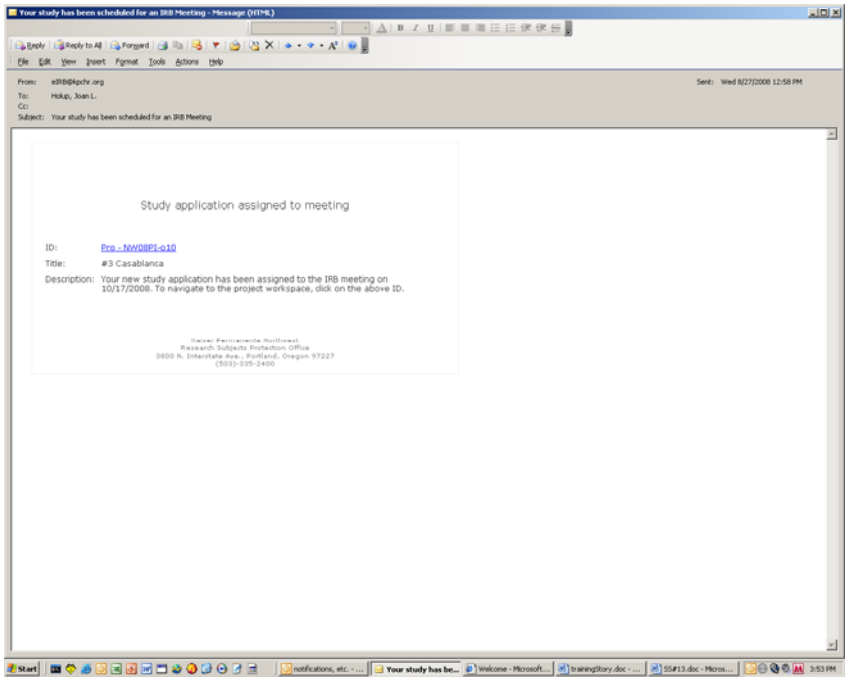
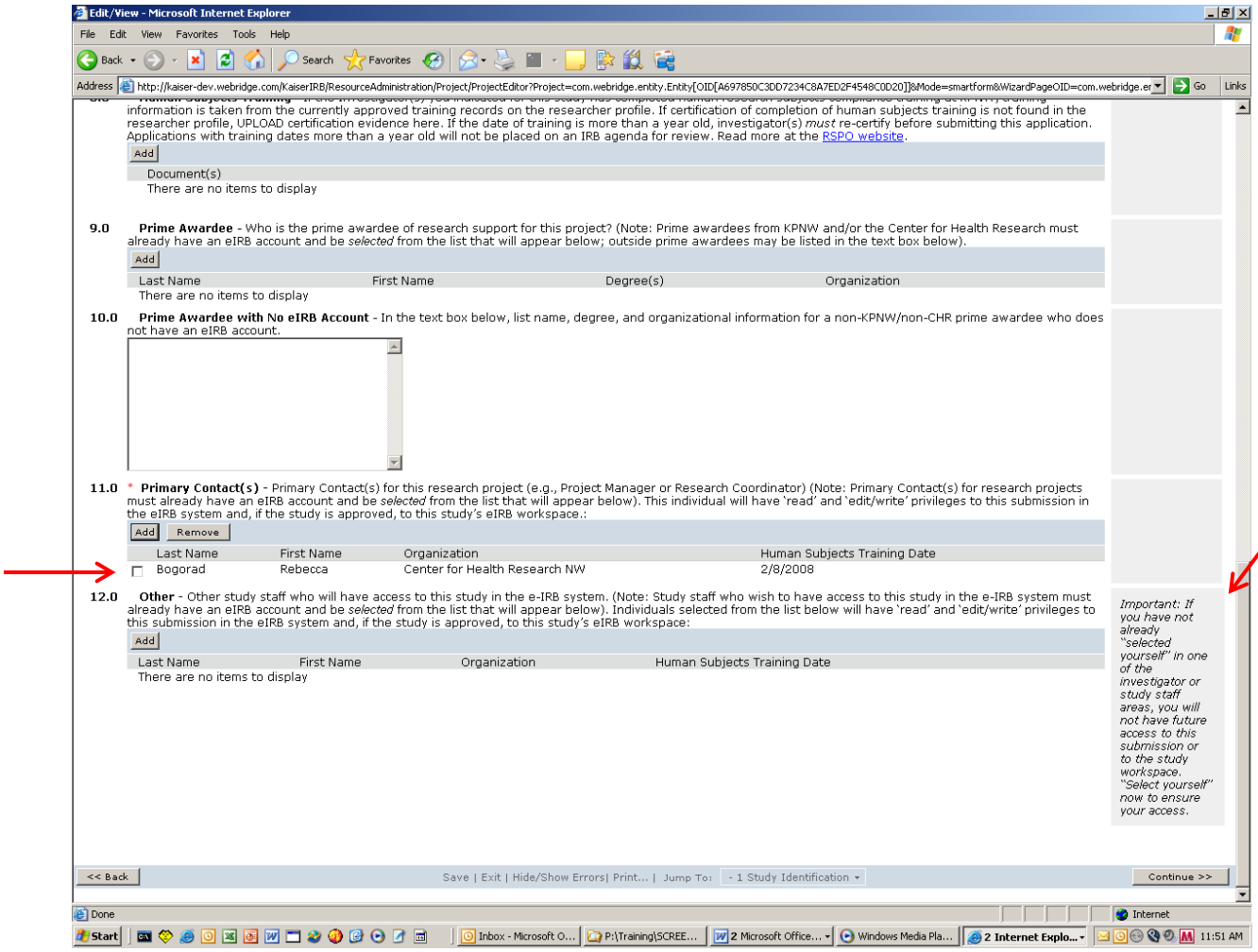


Figure 9a

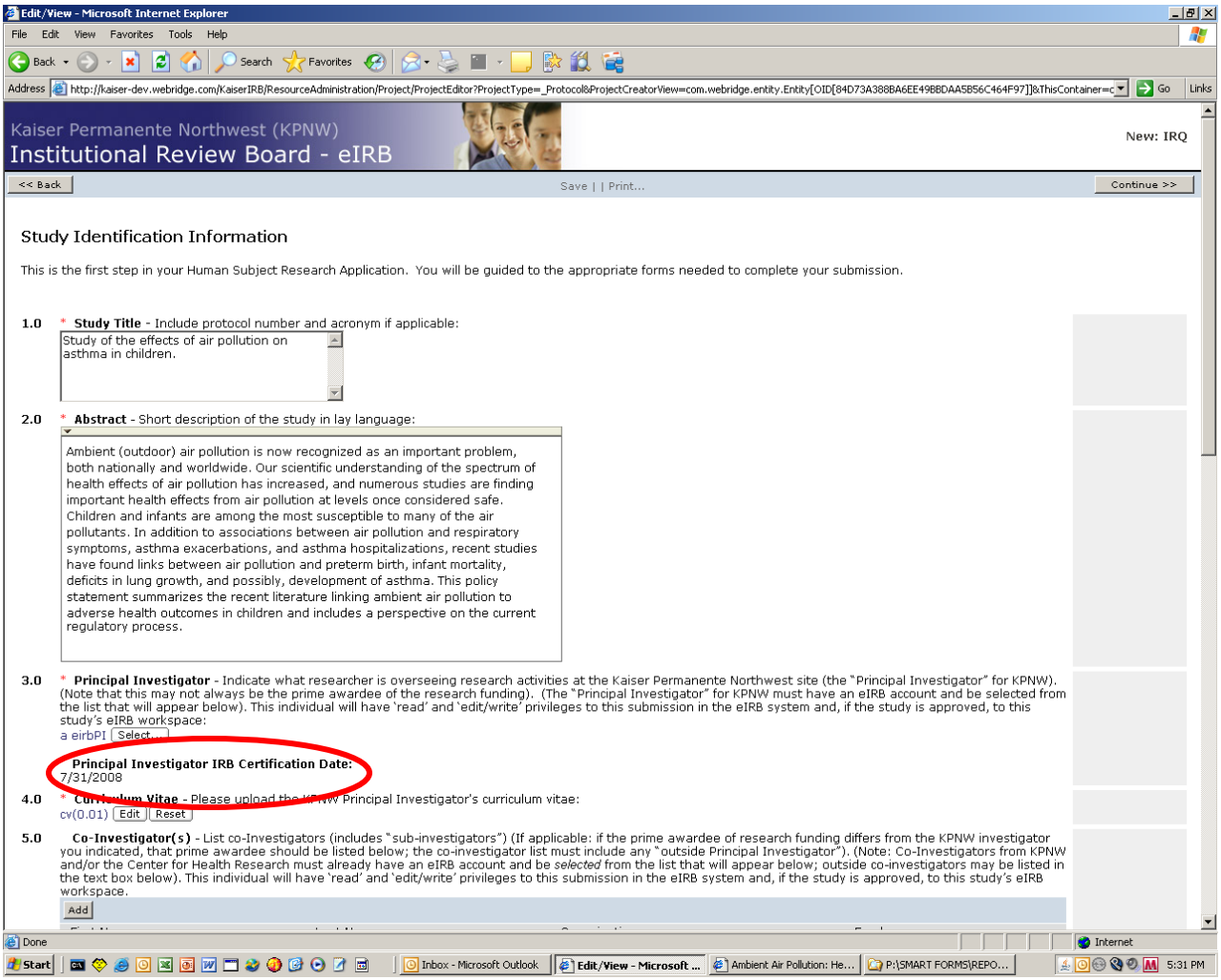

Edit/View - Microsoft Internet Explorer
Document(s)
There are no items to display
9.0 Prime Awardee - Who is the prime awardee of research support for this project? (Note: Prime awardees from KPNW and/or the Center for Health Research must already have an eIRB account and be selected from the list that will appear below; outside prime awardees may be listed in the text box below).
Last Name First Name Degree(s) Organization
There are no items to display
10.0 Prime Awardee with No eIRB Account - In the text box below, list name, degree, and organizational information for a non-KPNW/non-CHR prime awardee who does not have an eIRB account.
11.0 * Primary Contact(s) - Primary Contact(s) for this research project (e.g., Project Manager or Research Coordinator) (Note: Primary Contact(s) for research projects must already have an eIRB account and be selected from the list that will appear below). This individual will have 'read' and 'edit/write' privileges to this submission in the eIRB system and, if the study is approved, to this study's eIRB workspace.:
Last Name First Name Organization Human Subjects Training Date
Bogorad Rebecca Center for Health Research NW 2/8/2008
12.0 Other - Other study staff who will have access to this study in the e-IRB system. (Note: Study staff who wish to have access to this study in the e-IRB system must already have an eIRB account and be selected from the list that will appear below). Individuals selected from the list below will have 'read' and 'edit/write' privileges to this submission in the eIRB system and, if the study is approved, to this study's eIRB workspace:
Last Name First Name Organization Human Subjects Training Date
There are no items to display
Important: If you have not already "selected yourself" in one of the investigator or study staff areas, you will not have future access to this submission or to the study workspace. "Select yourself" now to ensure your access.
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - 1 Study Identification
Continue >>

Help Text is in this gray area on the right of the page.

Figure 10

Human subjects training

The date of completion of human subjects training will be stored in user profiles. Information will be imported from the training system's database into the eIRB system weekly. If you, or someone on the study submission, has just completed human subjects training, and if the submission must go in right away, contact the eIRB Help Desk to request an unscheduled/immediate system update (see Figure 11).


Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
New: IRQ
<< Back
Save | | Print...
Continue >>
Study Identification Information
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3.0 * Principal Investigator - Indicate what researcher is overseeing research activities at the Kaiser Permanente Northwest site (the "Principal Investigator" for KPNW). (Note that this may not always be the prime awardee of the research funding). (The "Principal Investigator" for KPNW must have an eIRB account and be selected from the list that will appear below). This individual will have 'read' and 'edit/write' privileges to this submission in the eIRB system and, if the study is approved, to this study's eIRB workspace:
a eirbPI Select...
Principal Investigator IRB Certification Date:
7/31/2008
4.0 * Curriculum Vitae - Please upload the KPNW Principal Investigator's curriculum vitae:
cv(0.01) Edit Reset
5.0 Co-Investigator(s) - List co-Investigators (includes "sub-investigators") (If applicable: if the prime awardee of research funding differs from the KPNW investigator you indicated, that prime awardee should be listed below; the co-investigator list must include any "outside Principal Investigator"). (Note: Co-Investigators from KPNW and/or the Center for Health Research must already have an eIRB account and be selected from the list that will appear below; outside co-investigators may be listed in the text box below). This individual will have 'read' and 'edit/write' privileges to this submission in the eIRB system and, if the study is approved, to this study's eIRB workspace.
Add
Done
Internet
Start
Inbox - Microsoft Outlook
Edit/View - Microsoft ...
Ambient Air Pollution: He...
P:\SMART FORMS\REPO...
5:31 PM

Figure 11

Updating study staff

The "Edit study staff" activity (see Figure 12) located under "My Activities" in the study workspace allows you to quickly change the study staff who either have been added to or have left a study; (to learn more about 'activities' generally, see: *Glossary: Understanding "Activities"* near the end of this manual). Updating study staff is important to ensure appropriate staff are receiving notifications from the IRB regarding the study (e.g., continuing review reminders). This "Edit study staff" activity is available in most states once a study has been submitted, including pre- and post-approval states. IRB approval is NOT required to change study staff on an approved study. Editing investigators on an approved study *does* require a modification request submission.

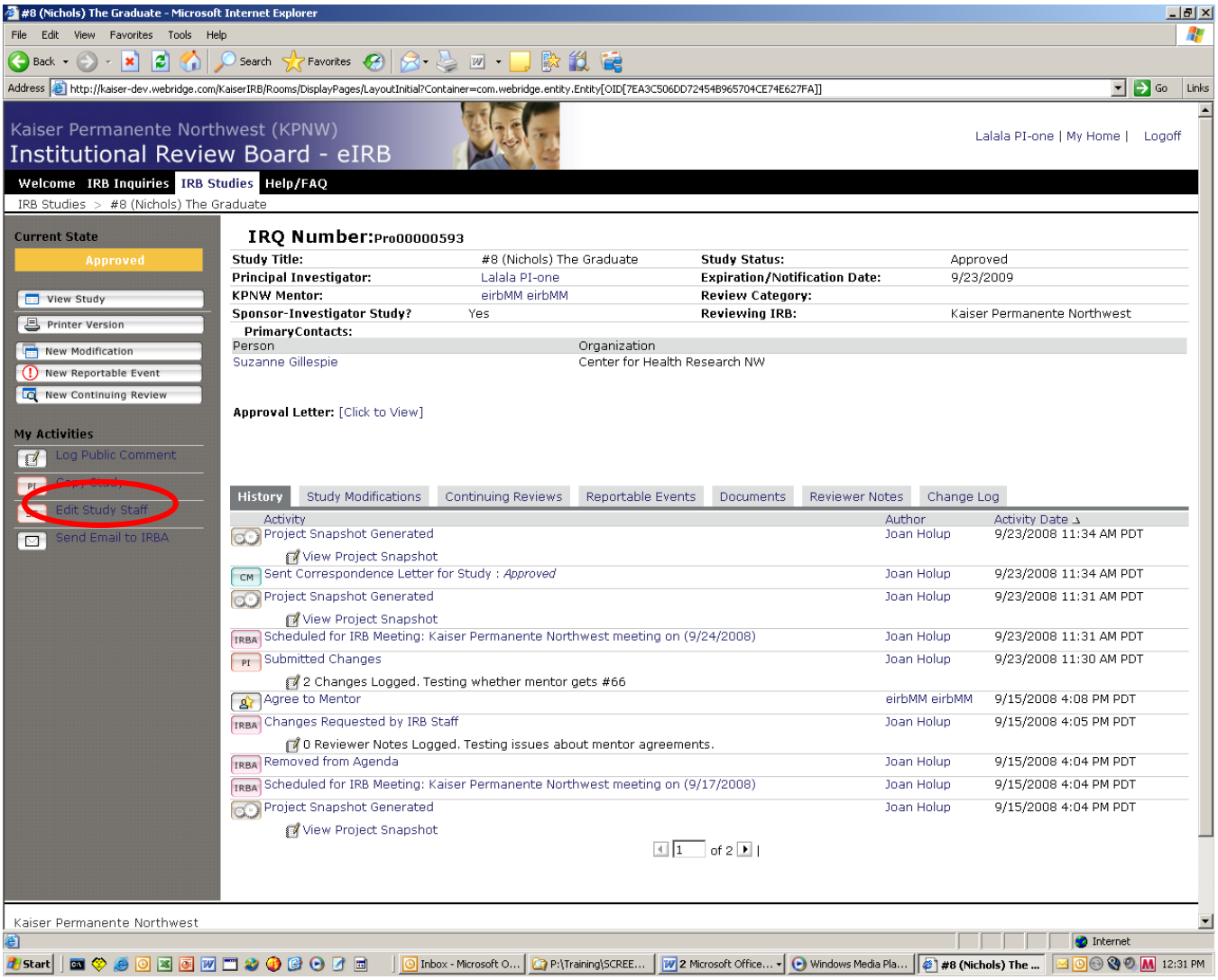


Figure 12

NAVIGATING THE INITIAL REVIEW QUESTIONNAIRE (IRQ)

Understanding "Help Text Area"

Throughout the IRQ you can find the light-gray "Help Text Area" located on the right section of each page (see Figure 10 a few pages back). The "Help Text Area" contains useful hints and explanations, all of which will assist you in filling out the eIRB forms.

Searching lists

For some answers you will be asked to first try to select from a list rather than just typing-in your answer. For example, in the funder/sponsor questions you are asked to select from a list that is already within the eIRB system. In such areas, it may be helpful for you to use the following example of a search technique: If your funder is 'The Cancer Society' but you are not sure "The" is really part of the funder's name, you can try to use a percentage sign as follows: enter "%cancer". All funders and sponsors with the word "cancer" anywhere within their name will be filtered and listed. Then, you can select your funder if it is found on the filtered list. If the funder/sponsor is not on the list in the system, enter the name in the text box provided.

Using the form drop-down list to 'Jump To' pages

The form drop-down list box (see Figure 13) is a convenient way to navigate through the IRQ if you do not wish to use the "Continue" button and if you already know the name of the

section that you would like to modify. You must click on the down arrow next to the 'jump to' menu; do *not* click the text that says "Jump to Menu". The 'Jump To' menu will highlight your current page/screen in red font. It is very important to note that the form drop-down list box will display only the list of form sections that are already known to apply to your study. As you move through the form, the system may augment the list if new required branches of the forms become apparent. However, it is highly recommended that you use the "Continue" button to progress through the application, as the system will then be smart enough to walk you through the proper branching and the submission will seem most 'logical' in terms of the progression of questions.

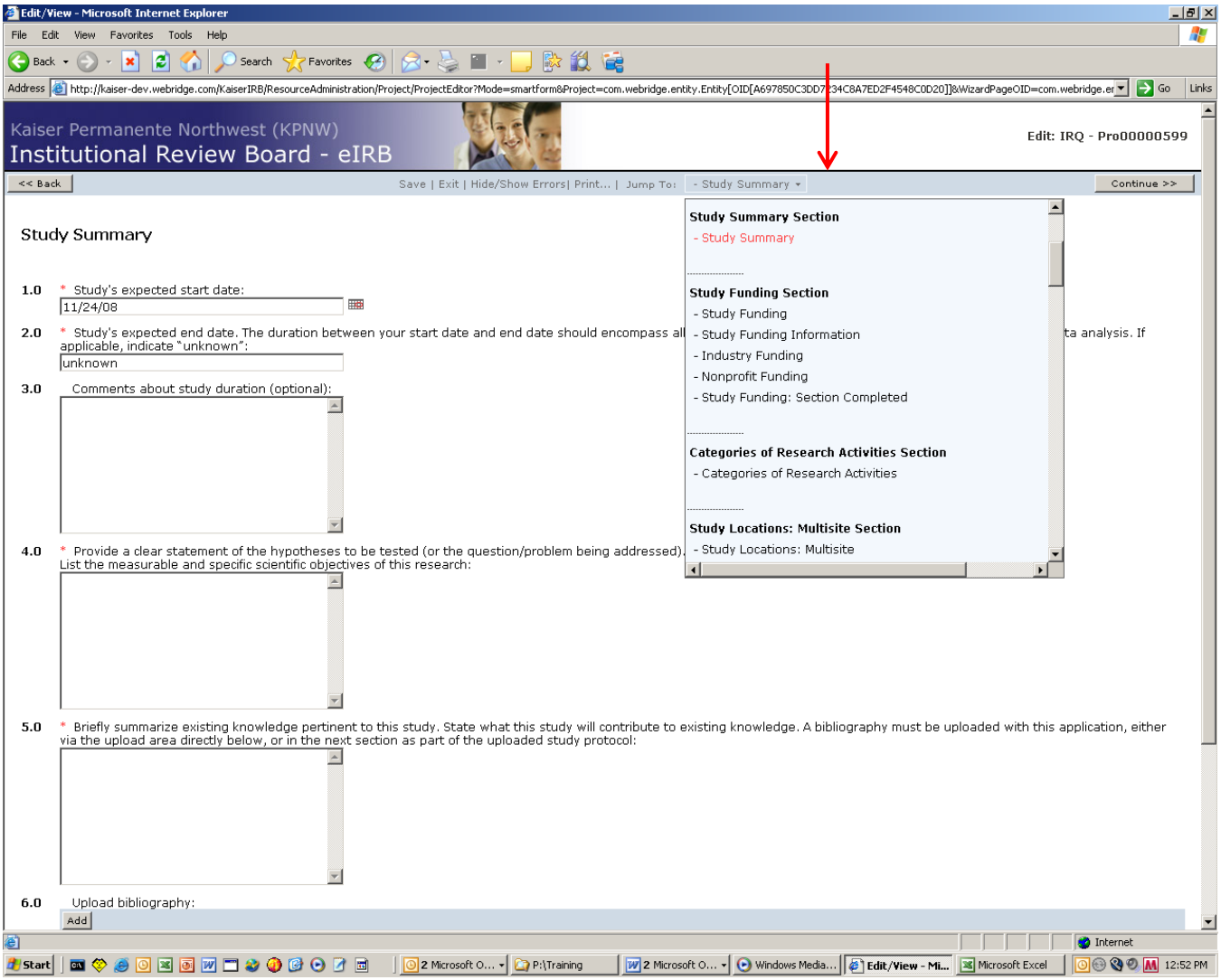

Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Edit: IRQ - Pro00000599
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - Study Summary
Continue >>
Study Summary
1.0 * Study's expected start date:
11/24/08
2.0 * Study's expected end date. The duration between your start date and end date should encompass all
applicable, indicate "unknown":
unknown
3.0 Comments about study duration (optional):
4.0 * Provide a clear statement of the hypotheses to be tested (or the question/problem being addressed).
List the measurable and specific scientific objectives of this research:
5.0 * Briefly summarize existing knowledge pertinent to this study. State what this study will contribute to existing knowledge. A bibliography must be uploaded with this application, either via the upload area directly below, or in the next section as part of the uploaded study protocol:
6.0 Upload bibliography:
Add
Study Summary Section
- Study Summary
Study Funding Section
- Study Funding
- Study Funding Information
- Industry Funding
- Nonprofit Funding
- Study Funding: Section Completed
Categories of Research Activities Section
- Categories of Research Activities
Study Locations: Multisite Section
- Study Locations: Multisite

Figure 13

Saving the information you have entered

There are two ways to save information you have entered into Initial Review Questionnaire, Continuing Review, Reportable Events, and Modification Request forms. You may use the "Continue" button to automatically save all data entered into a form thus far. Or, you may use the "Save" option. The latter will save the information, but will not automatically lead you to the next page/screen.

Using Hide/Show Errors

The Hide/Show Errors link, located in both the upper as well as the lower center, of the form allows you to check for any required questions that have been omitted. The links that display in the Errors/Warning messages window allow you to jump directly to the required question and answer it. Once you have answered the question, click on the "Save" link and then click on the "Refresh" button located in the lower right section of the page. Repeating this process will remove errors from the list as they are corrected until there are no errors left**.** *(To turn off the error display entirely, click on the "Hide/Show Errors" one more time).* See Figure 14.

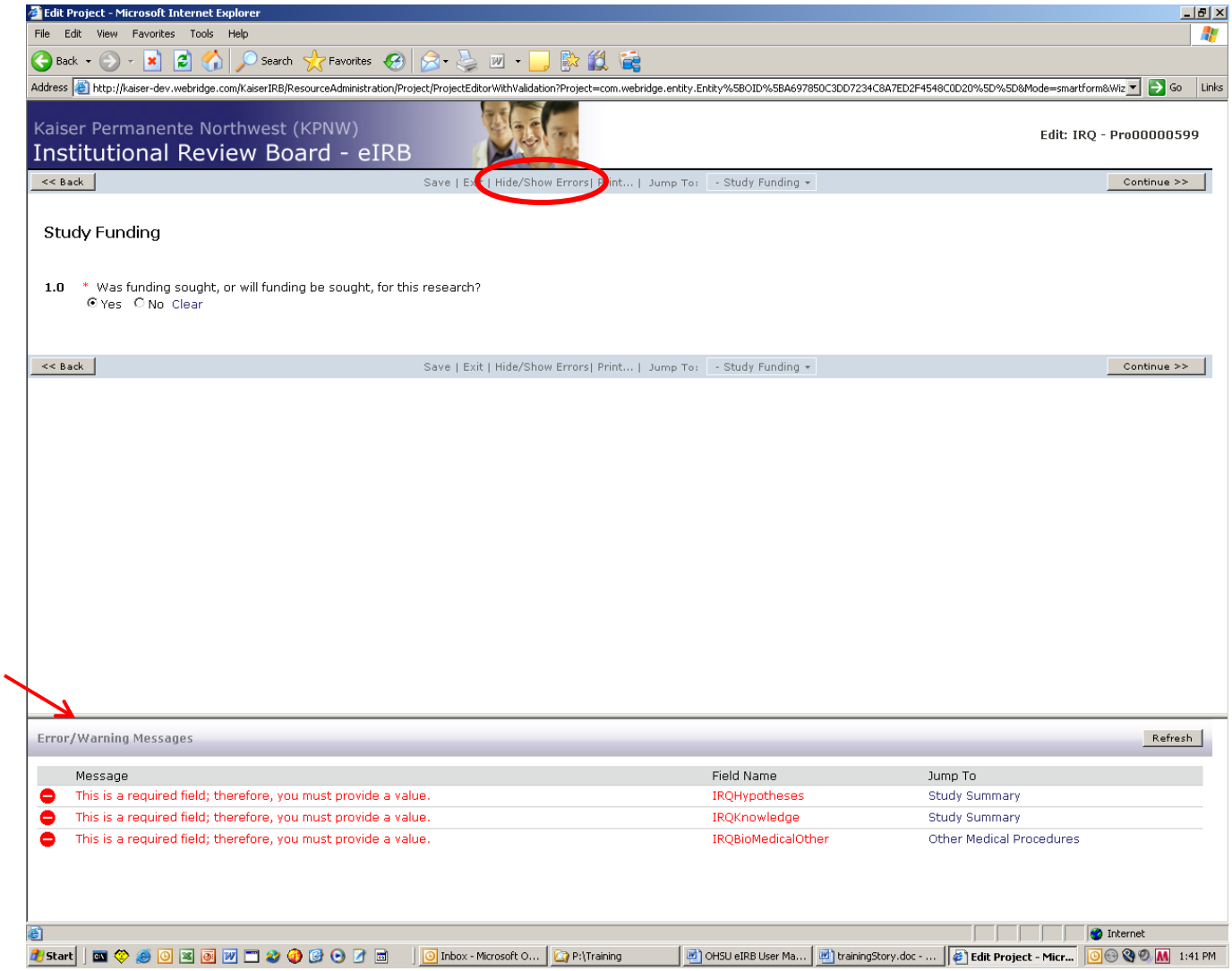


Figure 14

Please note that the PI will **not** be able to submit the study if there are any required questions that remain unanswered.

Exiting

Before exiting it is important to save your answers by clicking the "Save" link.

To exit the IRQ please use the "Exit" link. If applicable, when you click on the "Exit" link, a standard warning window will open asking you/reminding you to save your answers. If you have not saved your answers and *wish to*, click "OK" and the system will save your changes and automatically 'exit' you from the submission. If you have not saved your answers and do NOT *wish to save them*, click "No" and the system will not save your changes and automatically close your submission (see Figure 15).

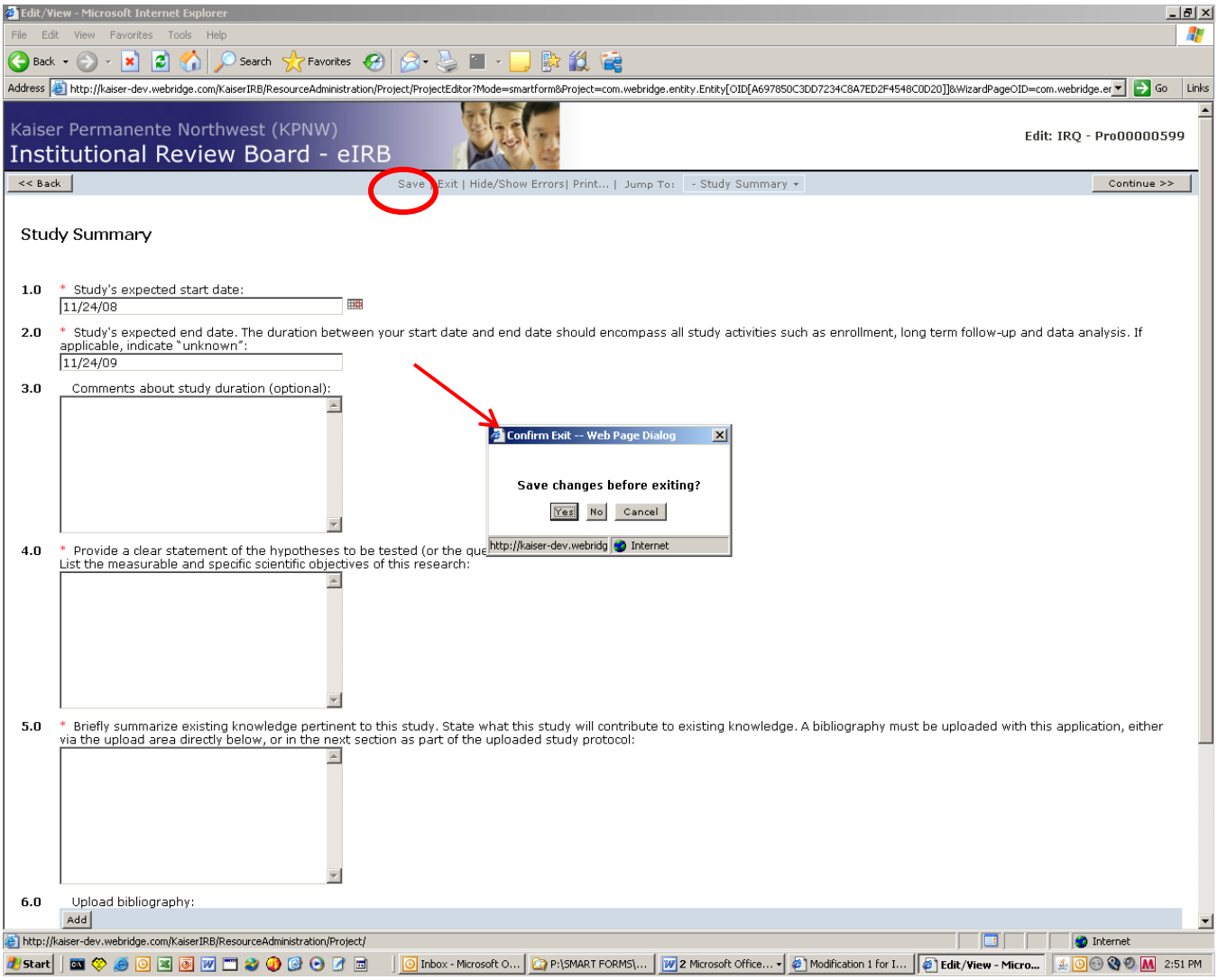

Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Edit: IRQ - Pro00000599
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - Study Summary
Continue >>
Study Summary
1.0 * Study's expected start date:
11/24/08
2.0 * Study's expected end date. The duration between your start date and end date should encompass all study activities such as enrollment, long term follow-up and data analysis. If applicable, indicate "unknown":
11/24/09
3.0 Comments about study duration (optional):
Confirm Exit -- Web Page Dialog
Save changes before exiting?
Yes
No
Cancel
4.0 * Provide a clear statement of the hypotheses to be tested (or the que
List the measurable and specific scientific objectives of this research:
5.0 * Briefly summarize existing knowledge pertinent to this study. State what this study will contribute to existing knowledge. A bibliography must be uploaded with this application, either via the upload area directly below, or in the next section as part of the uploaded study protocol:
6.0 Upload bibliography:
Add

Figure 15

Uploading documents

In various places in the eIRB forms, you may be asked to upload documents. For example, if you are doing primary data collection (collecting information or samples directly from participants), you will be asked to upload any recruitment materials to be used on the study (see Figure 16).

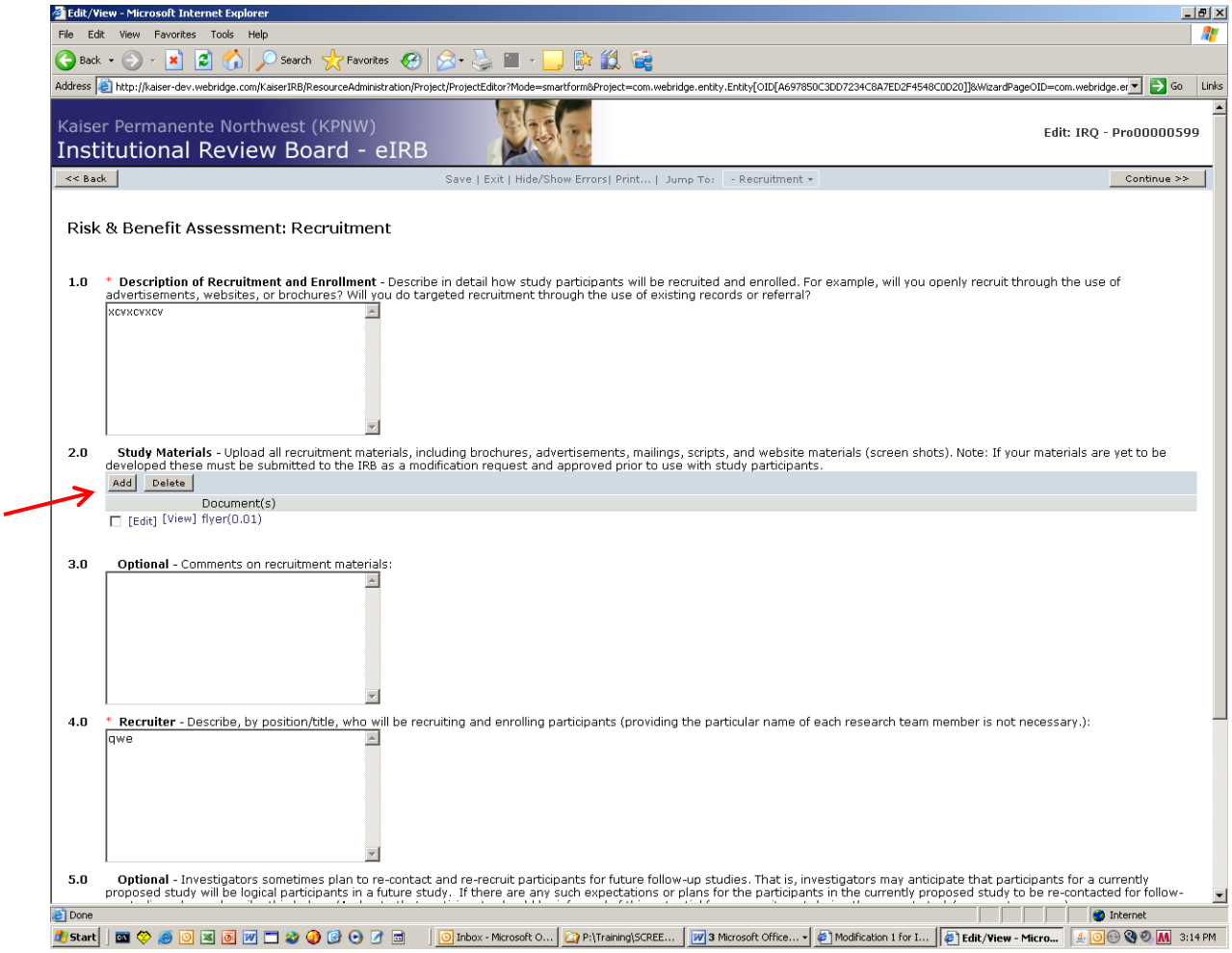

Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Edit: IRQ - Pro00000599
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - Recruitment
Continue >>
Risk & Benefit Assessment: Recruitment
1.0 * Description of Recruitment and Enrollment - Describe in detail how study participants will be recruited and enrolled. For example, will you openly recruit through the use of advertisements, websites, or brochures? Will you do targeted recruitment through the use of existing records or referral?
xcvxcvxcv
2.0 Study Materials - Upload all recruitment materials, including brochures, advertisements, mailings, scripts, and website materials (screen shots). Note: If your materials are yet to be developed these must be submitted to the IRB as a modification request and approved prior to use with study participants.
Add
Delete
Document(s)
[Edit] [View] flyer(0.01)
3.0 Optional - Comments on recruitment materials:
4.0 * Recruiter - Describe, by position/title, who will be recruiting and enrolling participants (providing the particular name of each research team member is not necessary.):
qwe
5.0 Optional - Investigators sometimes plan to re-contact and re-recruit participants for future follow-up studies. That is, investigators may anticipate that participants for a currently proposed study will be logical participants in a future study. If there are any such expectations or plans for the participants in the currently proposed study to be re-contacted for follow-
Done
Internet
Start
3:14 PM

Figure 16

In addition to the standard documents that are requested throughout the IRQ form (such as consent forms or protocol) there is a place for 'other' documents to be uploaded at the end of the submission. Use this option *if* you have progressed through the submission process to the end *and have not had a logical/designated place to upload a certain document* (see Figure 17). You are strongly encouraged to use this 'general' area only when there has been no other logical place to upload the material. Following this rule will help your study team and the IRB *later* when you need to make modification requests related to documents.

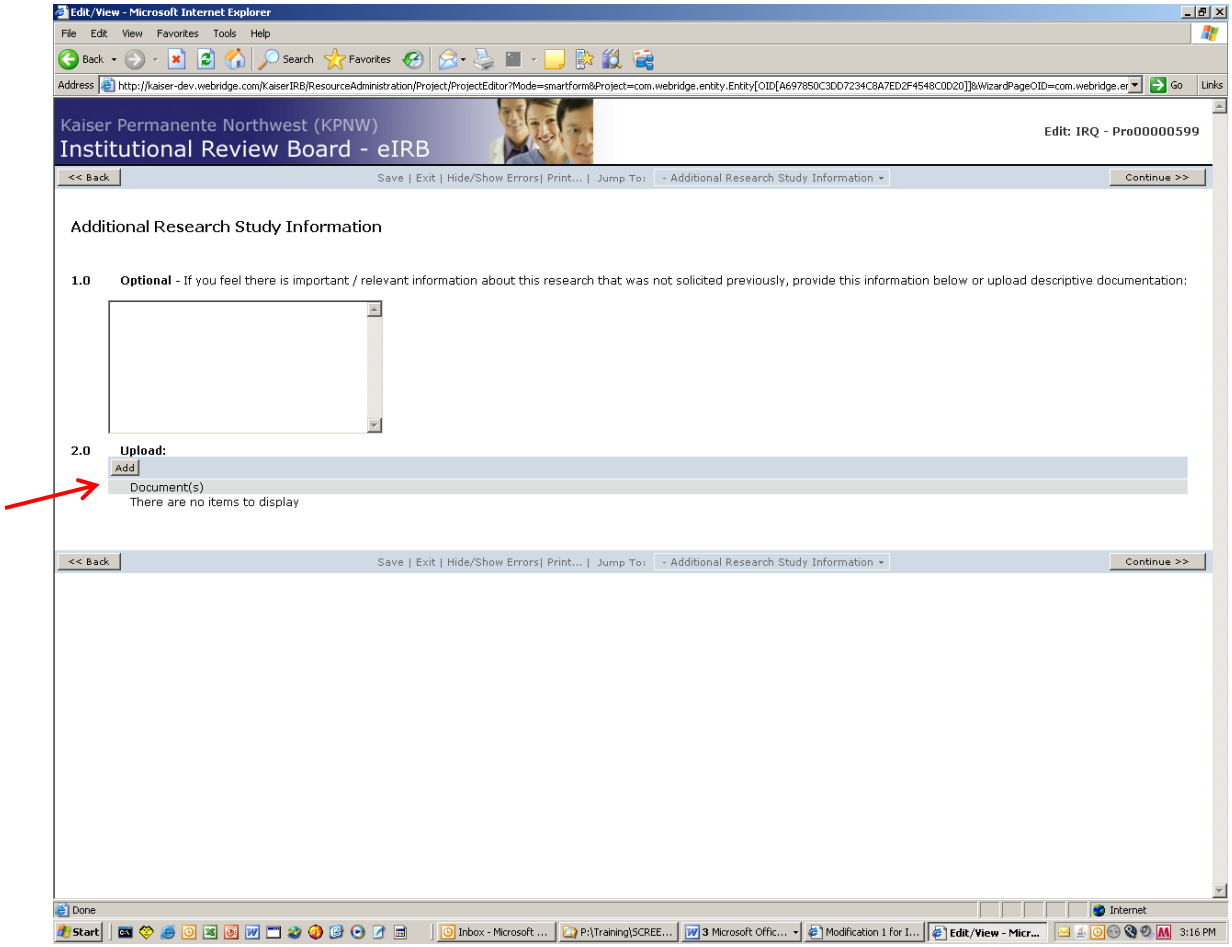


Figure 17

The eIRB will allow you to upload electronic documents of any type and format. It is important to keep in mind that the reviewer of these documents, such as an RSPO employee or IRB reviewers, must have the same software application as you to be able to open and read the uploaded document. When possible, use standard software applications available on KPNW workstations, such as Microsoft® Word, Excel, PowerPoint, and Adobe Acrobat Reader.

Most document upload areas allow you to upload multiple documents (if that is needed on your study). Click on the “Browse” button in order to locate the document you would like to upload. You may provide a title for the document(s) you upload. If you do not title the document(s), the file name(s) will be used as a default (see Figure 18).

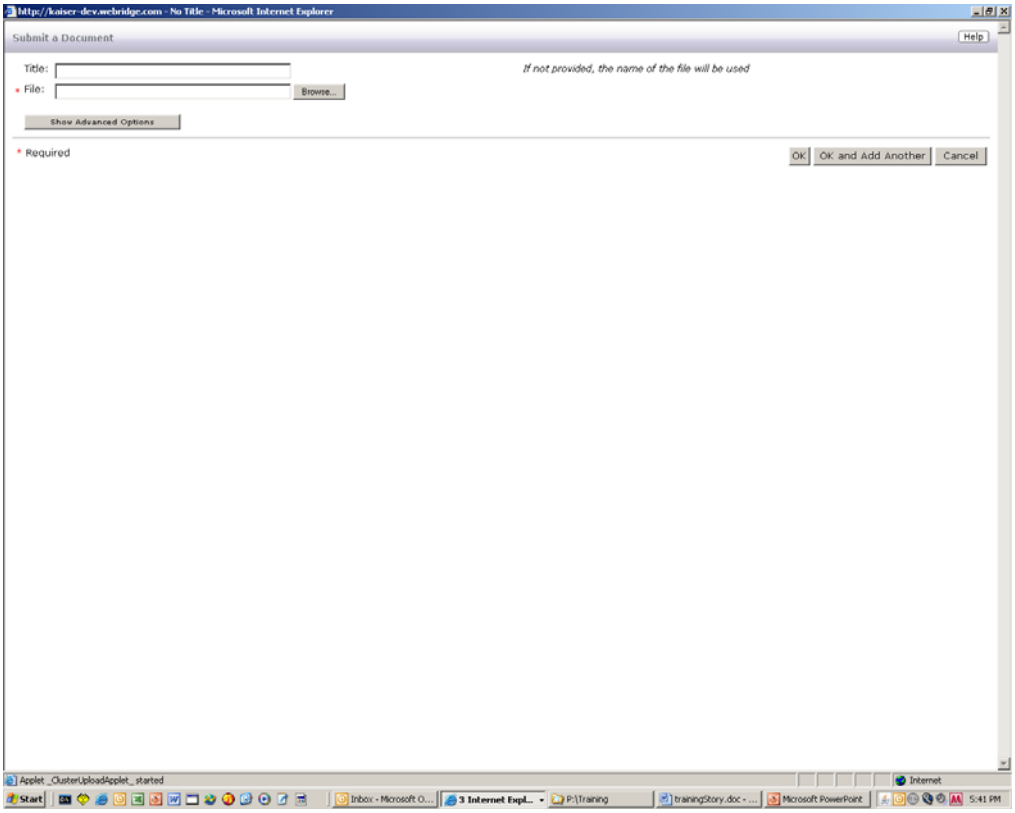


Figure 18

Once you have located the document on a network-drive, select the document, click the "Open" button (see Figure 19) and then click the "OK" button on the document upload window (or click "OK and Add Another" if you wish to upload multiple documents).

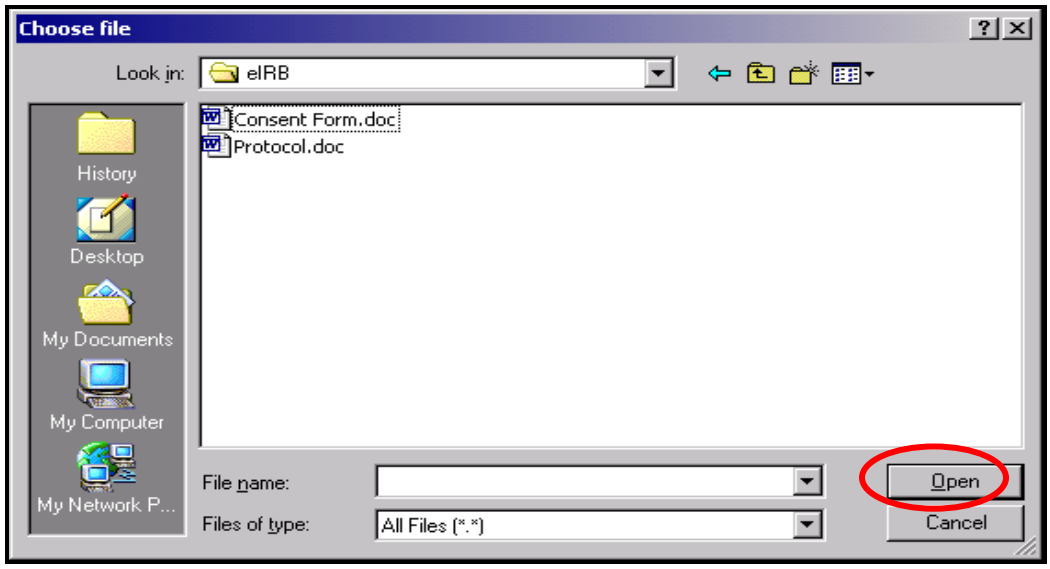


Figure 19

Deleting documents

If you mistakenly upload a document and need to remove it, place a checkmark next to the document and then hit "Delete". A message will appear asking if you are sure you want to delete the document. Indicate "OK" to delete the document. Be aware that deleted documents may not be retrieved within the eIRB. You would need to upload them again from your file service. See Figure 20.

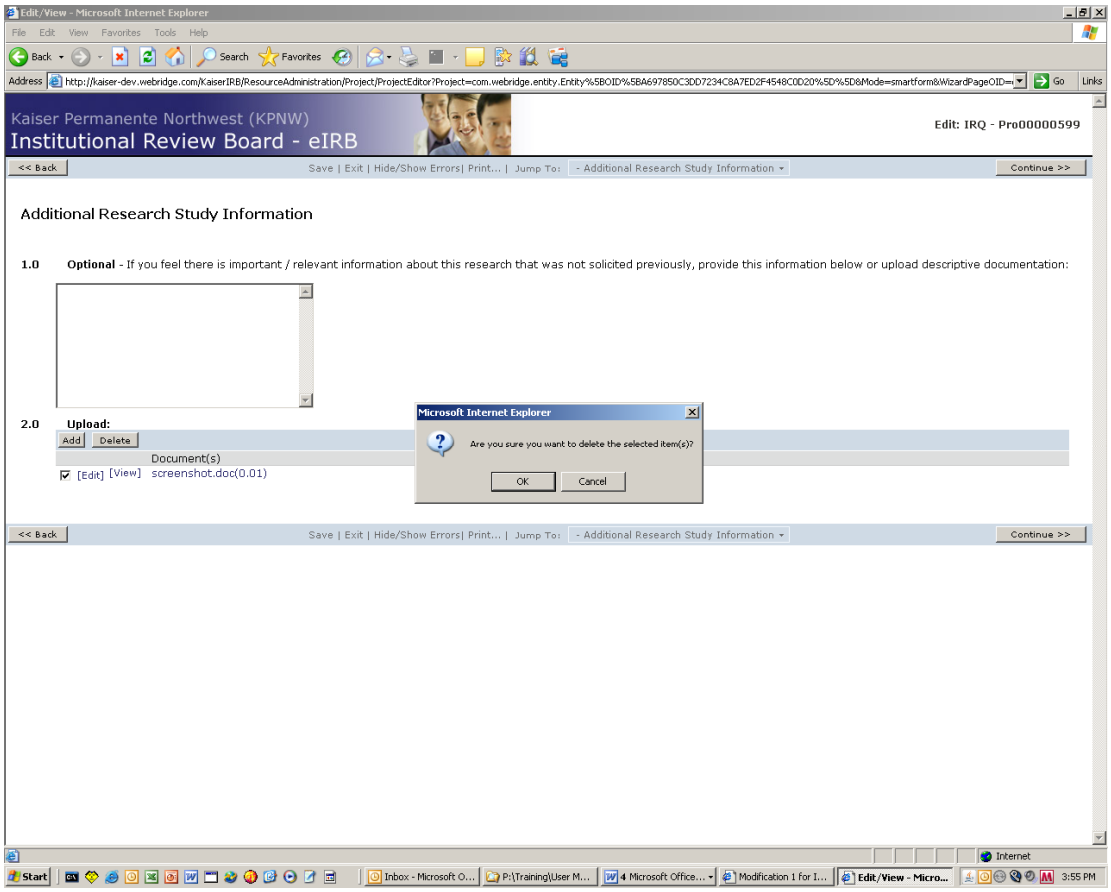


Figure 20

You may get the following (Figure 21) the first time you attempt to upload a document into the IRQ. Check the "Always trust" and click on "Run".

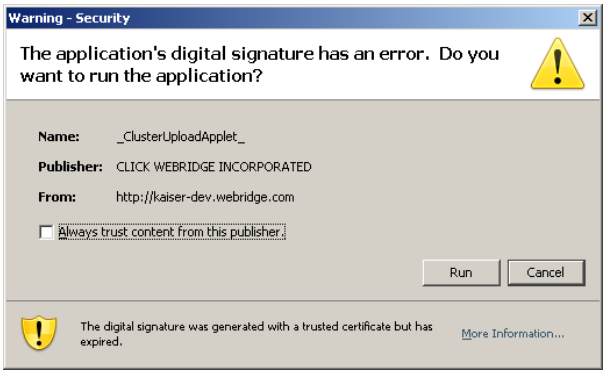


Figure 21

You may also be presented with the following message if the eIRB system is *already* in the process of uploading a file into your submission and you attempt to upload the file again: "You have already submitted the current form. Please wait and the operation will be completed momentarily".

Editing / replacing uploaded documents

If you wish to upload an edited or newer version of the document, click the "Edit" link in front of the document and repeat the upload procedure. Click the "OK" button in order to close the window. The document version will be automatically incremented (Version 0.01 to Version 0.02, etc.)

The eIRB maintains a history of all subsequently uploaded documents and allows you to rollback to a previous version. This function can be accomplished by clicking the "Edit" link in front of the document, and then by clicking on the "Show Advanced Option" button. Once the advanced options are displayed, click on the "History & Roll Back" link. You may now click on a previous version of a document to view it, or select the document you wish to "rollback to", followed by clicking the "OK" button.

Scanning

All study documents must be submitted through the eIRB system. Therefore, all study documents that are not already in digital/electronic format will need to be scanned so they can be uploaded into the system. Investigators/study staff may approach CHR administrative assistants with scanning requests. Such requests will be turned around within two business days.

The scanning procedure will be as follows: The project manager/PI will give the hardcopy document(s) to the administrative assistant and indicate where the administrative assistant should place the scanned document within the chr_open drive. Within two business days, the administrative assistant will scan the document on the copier and move the scanned document from the chr_scangroup drive to the chr_open drive. After scanning, the administrative assistant will notify the project manager/PI that the scan is done. The project manager/PI will move the document from the chr_open drive to the project drive.

STUDY WORKSPACE OVERVIEW

When you create a Study, Continuing Review, Reportable Event, Modification, or IRQ Inquiry, a comprehensive area referred to as the "workspace" is created, which displays useful information about the submission (see Figure 22).

In a 'study' workspace, the study's "IRQ number" is displayed in bolded letters near the top. When speaking with eIRB technical support staff or with RSPO staff, refer to the last digits of the IRB number, omitting the zeros. In Figure 22, this would be number "593".

The yellow area indicates the **Current State** of the review process for the particular submission. As the review progresses, the information here will change. (*See GLOSSARY: Understanding "Current States" for more detail*).

My Activities lists the activities available to you in the *Current State* of the review process for the particular submission. As the review progresses, available activities will change. (*See GLOSSARY: Understanding "Activities" for more detail*).

Note: When a submission is in a 'pre-submission' state, this is the area where the PI would find the 'Submit' activity listed.

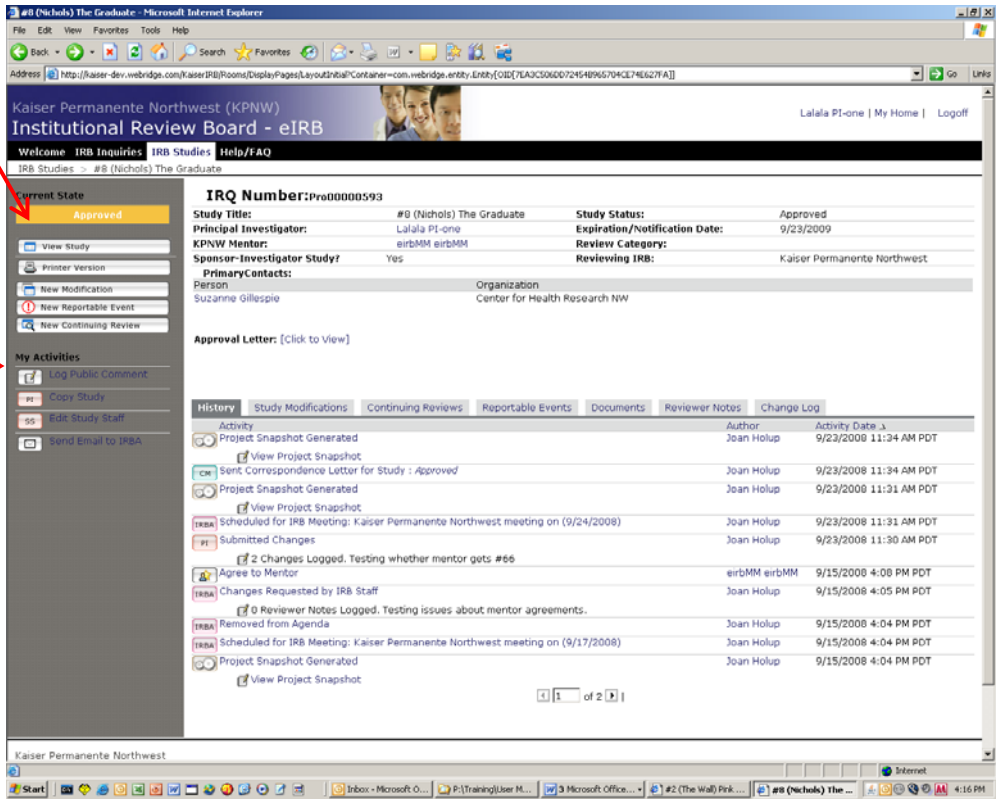


Figure 22

Study Workspace Details (Refer to Figure 22)

- "Study Title" displays the first 50 characters of the title entered into the first field on the IRQ.
- Your "Old IRB #", e.g., NW-08MHorn-04, will be displayed as the IRQ Number only if you have converted an existing study from paper.
- Once the study has been approved and given an IRB approval expiration date, that date will display on the workspace.
- If the study has a 'Mentor' assigned, the mentor's name will appear in the workspace.
- If the study has a KPNW sponsor-investigator, "yes" will display. (This is for IRB administrative interest related to FDA-regulated studies only).
- Information for the primary contacts listed on the IRQ is displayed.
- If there is an 'Approval' letter for the study, a link will be available to view.
- The tabs on the study workspace contain and, if clicked, <u>will display:</u>

    - Events associated with the IRB review of the study (see History tab, figure 22). Note that new studies and *other* types of submissions (Study Modifications; Continuing Reviews; and Reportable Events) also have their *own* history tabs that display events in their review process.

    - Submissions subsequent to the initial submission (Study Modifications; Continuing Reviews; and Reportable Events tabs, see figure 22a);

- Current versions of documents. When new study documents are 'approved,' or once documents are subsequently approved through a Modification Request, this tab will automatically 'update' to display current versions; (Documents tab, see figure 22b)

and

- If applicable, reviewer notes and a change log for the study.

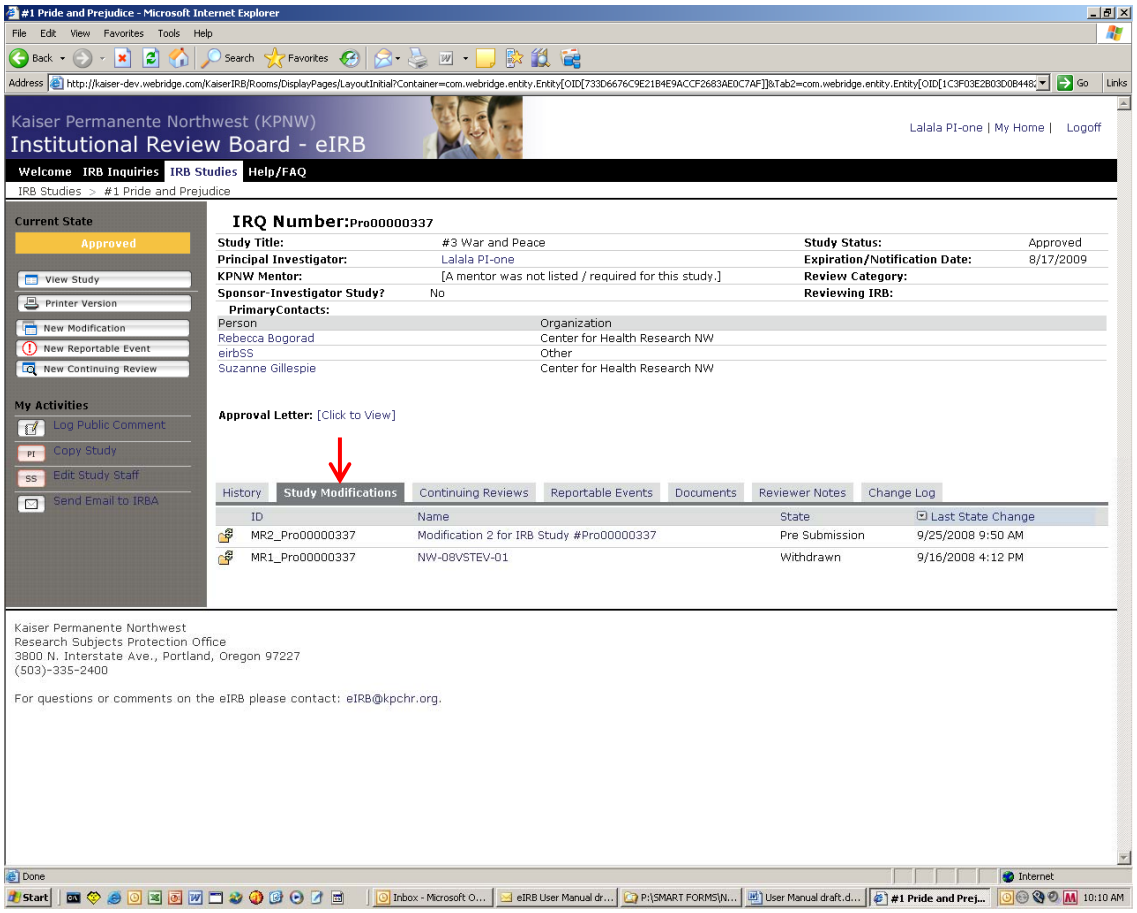


Figure 22a

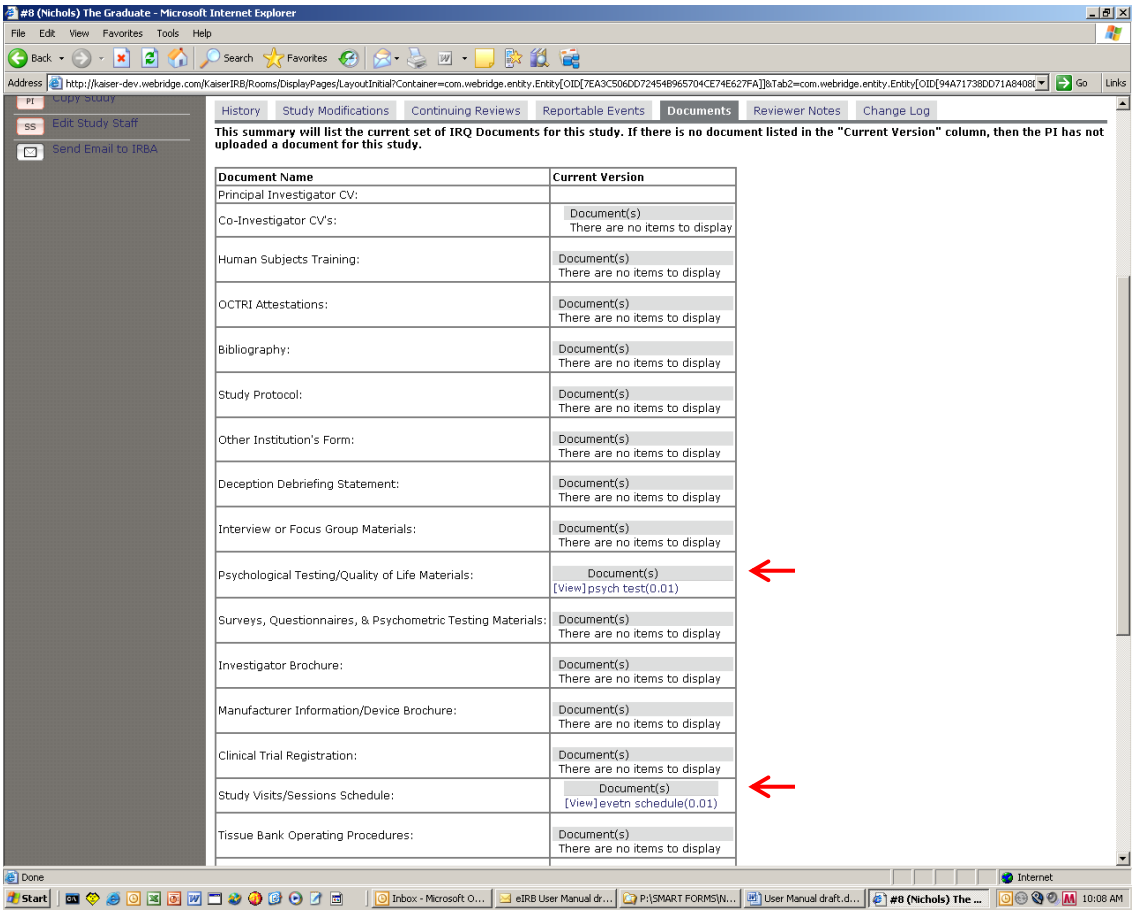


Figure 22b

Printing, saving, and documenting submissions

There is a Printer Version feature within the system for printing hardcopies of the submissions and saving a copy of the submission as an electronic file. See the Printer Version button in the left area of the submission workspace (see Figure 22). That said, you are encouraged to primarily rely on the eIRB system itself for 'documentation', since the system is designed to provide a sufficient project history, record of submissions, and record of IRB approvals. KPNW's adoption of an eIRB system can result in cost savings and significant environmental benefits, if fewer hardcopies are associated with the IRB process. The Project Snapshot that runs at designated points in the review process and is found in the History tab is another method used to 'freeze and capture a snapshot in time' of a study submission.

Submitting

Only the PI on a study has the option to submit the new study, continuing review, reportable event, or modification request (equivalent to a signature on paper).

If you are not the investigator and you have drafted a submission form: Once you have drafted/filled out the initial review questionnaire (IRQ), continuing review, reportable event, or modification request, you must then notify the PI that the draft is ready for him or her to review and submit. You may provide the PI with the IRQ number and/or the study title for reference. If she or he is listed as the PI within the study submission (see question 3 on figure 11 earlier in this manual), the drafted submission should display in the PI's inbox in a state of 'pre-submission'.

The PI must submit the form (regardless of who drafted the form. Once the PI has ensured that the submission is accurate and ready for IRB review, the PI will click on the "Submit" activity located on the left section of the submission workspace page under My Activities. If it is a new study submission, the PI will be presented with, and will need to check, a number of attestations as part of the 'submit' activity. Once the submit action has been completed, the submission will move to a state of 'IRB Staff Review', and will have entered the review process.

CONVERTING EXISTING HARDCOPY STUDIES INTO THE eIRB

If your active study is currently on paper and you are planning to do any IRB submission (including continuing review) soon, you MUST first convert your active hardcopy study to the eIRB, by selecting "New Study" located in the upper left section of the "My Home" page (see Figure 23).

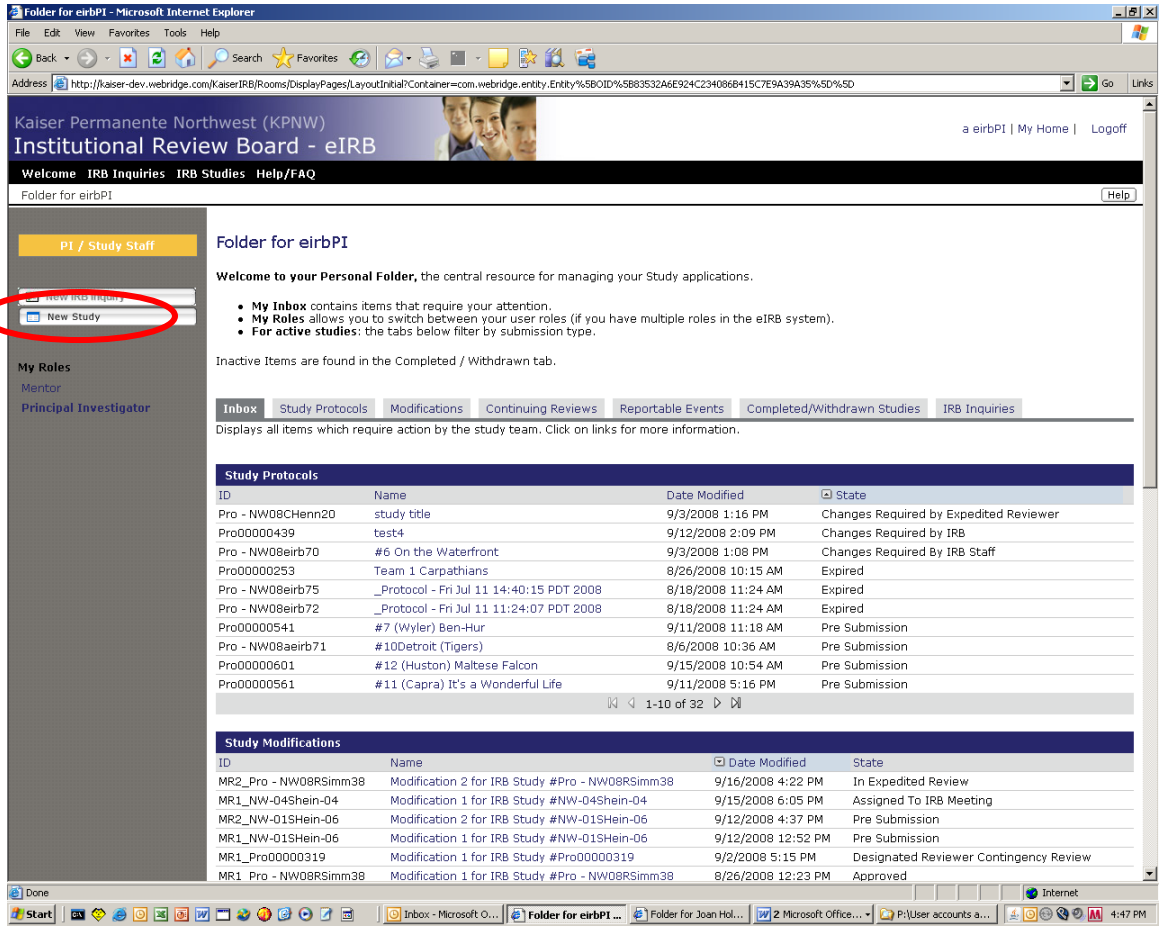

Folder for eirbPI - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
a eirbPI | My Home | Logoff
Welcome IRB Inquiries IRB Studies Help/FAQ
Folder for eirbPI
Help
PI / Study Staff
New Study
My Roles
Mentor
Principal Investigator
Folder for eirbPI
Welcome to your Personal Folder, the central resource for managing your Study applications.
My Inbox contains items that require your attention.
My Roles allows you to switch between your user roles (if you have multiple roles in the eIRB system).
For active studies: the tabs below filter by submission type.
Inactive Items are found in the Completed / Withdrawn tab.
Inbox
Study Protocols
Modifications
Continuing Reviews
Reportable Events
Completed/Withdrawn Studies
IRB Inquiries
Displays all items which require action by the study team. Click on links for more information.
Study Protocols
ID Name Date Modified State
Pro - NW08CHenn20 study title 9/3/2008 1:16 PM Changes Required by Expedited Reviewer
Pro00000439 test4 9/12/2008 2:09 PM Changes Required by IRB
Pro - NW08eirb70 #6 On the Waterfront 9/3/2008 1:08 PM Changes Required By IRB Staff
Pro00000253 Team 1 Carpathians 8/26/2008 10:15 AM Expired
Pro - NW08eirb75 _Protocol - Fri Jul 11 14:40:15 PDT 2008 8/18/2008 11:24 AM Expired
Pro - NW08eirb72 _Protocol - Fri Jul 11 11:24:07 PDT 2008 8/18/2008 11:24 AM Expired
Pro00000541 #7 (Wyler) Ben-Hur 9/11/2008 11:18 AM Pre Submission
Pro - NW08aeirb71 #10Detroit (Tigers) 8/6/2008 10:36 AM Pre Submission
Pro00000601 #12 (Huston) Maltese Falcon 9/15/2008 10:54 AM Pre Submission
Pro00000561 #11 (Capra) It's a Wonderful Life 9/11/2008 5:16 PM Pre Submission
1-10 of 32
Study Modifications
ID Name Date Modified State
MR2_Pro - NW08RSimm38 Modification 2 for IRB Study #Pro - NW08RSimm38 9/16/2008 4:22 PM In Expedited Review
MR1_NW-04Shein-04 Modification 1 for IRB Study #NW-04Shein-04 9/15/2008 6:05 PM Assigned To IRB Meeting
MR2_NW-01SHein-06 Modification 2 for IRB Study #NW-01SHein-06 9/12/2008 4:37 PM Pre Submission
MR1_NW-01SHein-06 Modification 1 for IRB Study #NW-01SHein-06 9/12/2008 12:52 PM Pre Submission
MR1_Pro00000319 Modification 1 for IRB Study #Pro00000319 9/2/2008 5:15 PM Designated Reviewer Contingency Review
MR1_Pro - NW08RSimm38 Modification 1 for IRB Study #Pro - NW08RSimm38 8/26/2008 12:23 PM Approved
Done
Internet
Start
4:47 PM

Figure 23

The Initial Review Questionnaire (IRQ) will open. Enter information on the first page and click 'Continue' (remember to add your name to the study, as previously explained in this user-manual under the section titled "Adding Investigators and staff to the study submission.") On the next screen, for the type of submission, choose the option "A conversion of an existing (already IRB-approved) paper study into the eIRB" (see Figure 24). This will result in your progressing through an abbreviated version of the IRQ. Use the "Continue" button to navigate through the rest of the abbreviated questionnaire and answer all applicable questions. On the last page click "finish" to complete the questionnaire.

Once the IRQ for the converted study has been drafted, the study PI will 'submit' it. The RSPO office will expedite the 'Approval' of the study in the system in order to 'create' the

study within the eIRB. It will take a few days for the RSPO to process. Once the status changes to 'Approved', you will then have the option to create other submission types for the study, such as a continuing review, modification request, etc.

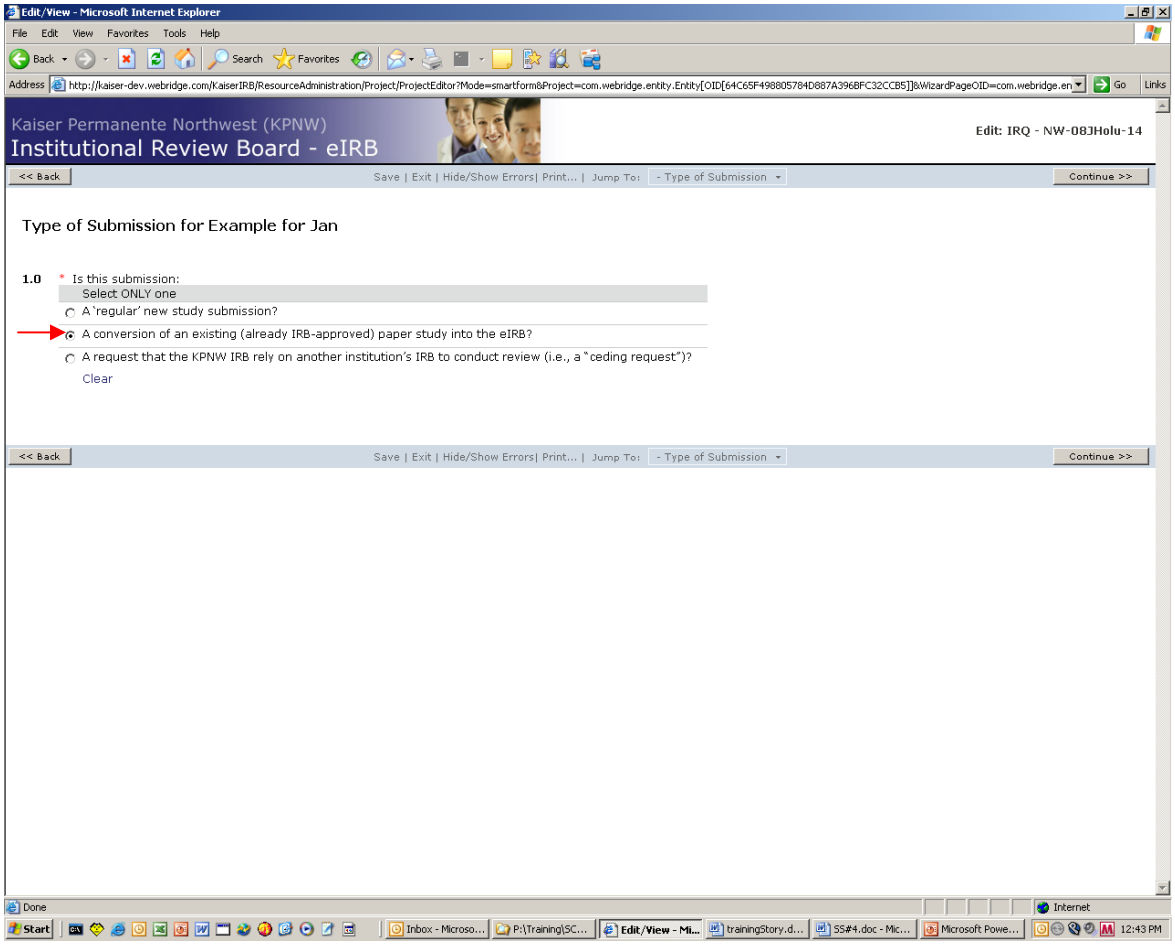


Figure 24

CREATING CONTINUING REVIEWS

Before you can create a continuing review, you must have an active/approved study in the eIRB. If you already have an active paper study, you may convert it in the eIRB. For details on converting an existing study, read the section of this user manual "Converting Existing Hardcopy Studies into the eIRB".

In order to create a continuing review, open your active study. In the left section of the page, click on the "New Continuing Review" button (see Figure 25). You may only initiate and be drafting one continuing review at a time on a given study, and you may only have one continuing review *submitted* at a time for any given study.

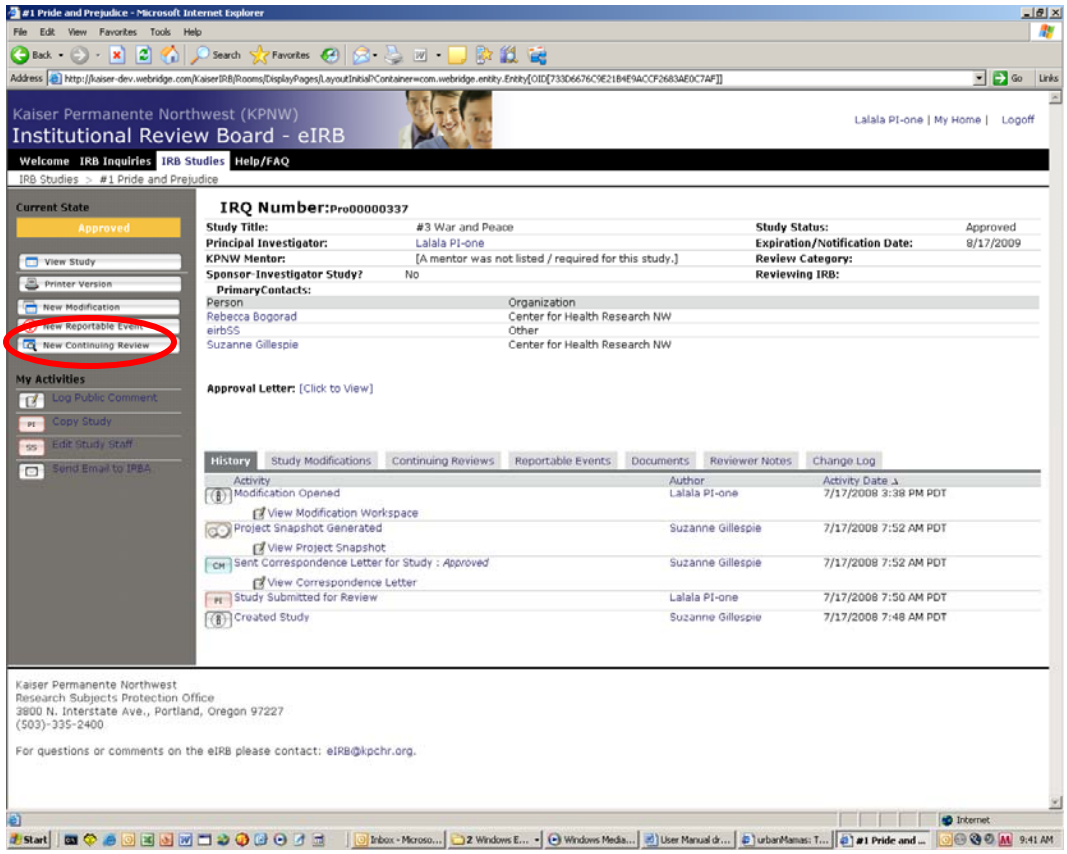

#1 Pride and Prejudice - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Lalala PI-one | My Home | Logoff
Welcome IRB Inquiries IRB Studies Help/FAQ
IRB Studies > #1 Pride and Prejudice
Current State
Approved
View Study
Printer Version
New Modification
New Reportable Event
New Continuing Review
My Activities
Log Public Comment
Copy Study
Edit Study Staff
Send Email to IRBA
IRQ Number:Pro00000337
Study Title: #3 War and Peace
Study Status: Approved
Principal Investigator: Lalala PI-one
Expiration/Notification Date: 8/17/2009
KPNW Mentor: [A mentor was not listed / required for this study.]
Review Category:
Sponsor-Investigator Study? No
Reviewing IRB:
PrimaryContacts:
Person Organization
Rebecca Bogorad Center for Health Research NW
eirbSS Other
Suzanne Gillespie Center for Health Research NW
Approval Letter: [Click to View]
History Study Modifications Continuing Reviews Reportable Events Documents Reviewer Notes Change Log
Activity Author Activity Date
Modification Opened Lalala PI-one 7/17/2008 3:38 PM PDT
View Modification Workspace
Project Snapshot Generated Suzanne Gillespie 7/17/2008 7:52 AM PDT
View Project Snapshot
Sent Correspondence Letter for Study : Approved Suzanne Gillespie 7/17/2008 7:52 AM PDT
View Correspondence Letter
Study Submitted for Review Lalala PI-one 7/17/2008 7:50 AM PDT
Created Study Suzanne Gillespie 7/17/2008 7:48 AM PDT
Kaiser Permanente Northwest
Research Subjects Protection Office
3800 N. Interstate Ave., Portland, Oregon 97227
(503)-335-2400
For questions or comments on the eIRB please contact: eIRB@kpchr.org.

Figure 25

Initially, the form will prompt you to indicate whether you are submitting a final or progress report, and ask for a short name that briefly describes your continuing review (see Figure 26). Use the "Continue" button located in the upper and in the lower right portion of the page to navigate through the form while answering all applicable questions page by page. On the last page click "finish" to complete the questionnaire. Once the continuing review is complete and error-free the PI should submit it for review using the "submit activity" (see submission section above).

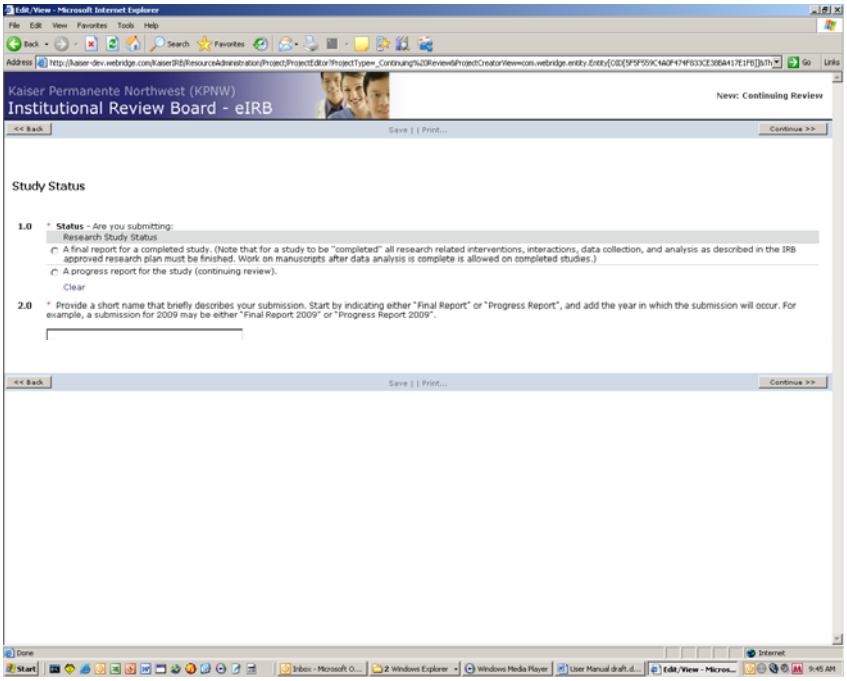

Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
New: Continuing Review
<< Back
Save | | Print...
Continue >>
Study Status
1.0 * Status - Are you submitting:
Research Study Status
A final report for a completed study. (Note that for a study to be "completed" all research related interventions, interactions, data collection, and analysis as described in the IRB approved research plan must be finished. Work on manuscripts after data analysis is complete is allowed on completed studies.)
A progress report for the study (continuing review).
Clear
2.0 * Provide a short name that briefly describes your submission. Start by indicating either "Final Report" or "Progress Report", and add the year in which the submission will occur. For example, a submission for 2009 may be either "Final Report 2009" or "Progress Report 2009".
<< Back
Save | | Print...
Continue >>

Figure 26

CREATING MODIFICATION REQUESTS

Your study must be "active and approved" in the eIRB before you submit a modification request on the study. (If you already have an active paper study, you may convert it in the eIRB. For details on converting an existing study, read the section of this user manual "Converting Existing Hardcopy Studies into the eIRB"). Once you have opened your active study, click on the "New Modification" button located in the left section of the study workspace (See Figure 27).

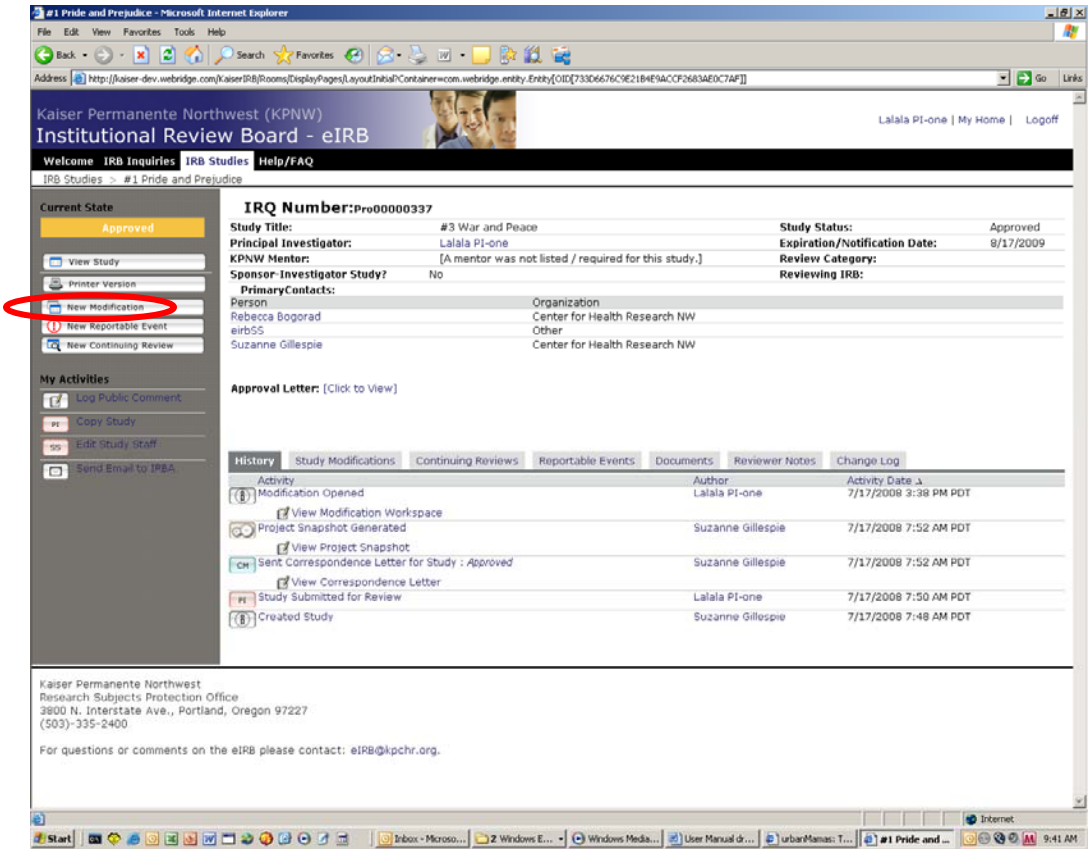

#1 Pride and Prejudice - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Lalala PI-one | My Home | Logoff
Welcome IRB Inquiries IRB Studies Help/FAQ
IRB Studies > #1 Pride and Prejudice
Current State
Approved
View Study
Printer Version
New Modification
New Reportable Event
New Continuing Review
My Activities
Log Public Comment
Copy Study
Edit Study Staff
Send Email to IRBA
IRQ Number:Pro00000337
Study Title: #3 War and Peace
Study Status: Approved
Principal Investigator: Lalala PI-one
Expiration/Notification Date: 8/17/2009
KPNW Mentor: [A mentor was not listed / required for this study.]
Review Category:
Sponsor-Investigator Study? No
Reviewing IRB:
PrimaryContacts:
Person Organization
Rebecca Bogorad Center for Health Research NW
eirbSS Other
Suzanne Gillespie Center for Health Research NW
Approval Letter: [Click to View]
History Study Modifications Continuing Reviews Reportable Events Documents Reviewer Notes Change Log
Activity Author Activity Date
Modification Opened Lalala PI-one 7/17/2008 3:38 PM PDT
View Modification Workspace
Project Snapshot Generated Suzanne Gillespie 7/17/2008 7:52 AM PDT
View Project Snapshot
Sent Correspondence Letter for Study : Approved Suzanne Gillespie 7/17/2008 7:52 AM PDT
View Correspondence Letter
Study Submitted for Review Lalala PI-one 7/17/2008 7:50 AM PDT
Created Study Suzanne Gillespie 7/17/2008 7:48 AM PDT
Kaiser Permanente Northwest
Research Subjects Protection Office
3800 N. Interstate Ave., Portland, Oregon 97227
(503)-335-2400
For questions or comments on the eIRB please contact: eIRB@kpchr.org.

Figure 27

On the first screen, provide a short name for your submission. The name of the submission should be a short description of the modification(s) being requested. For example, "Change PI"; "Revise Consent Form"; or "Change PI and revise consent and recruitment docs". The name of the submission should not exceed 50 characters with spaces (see Figure 28).

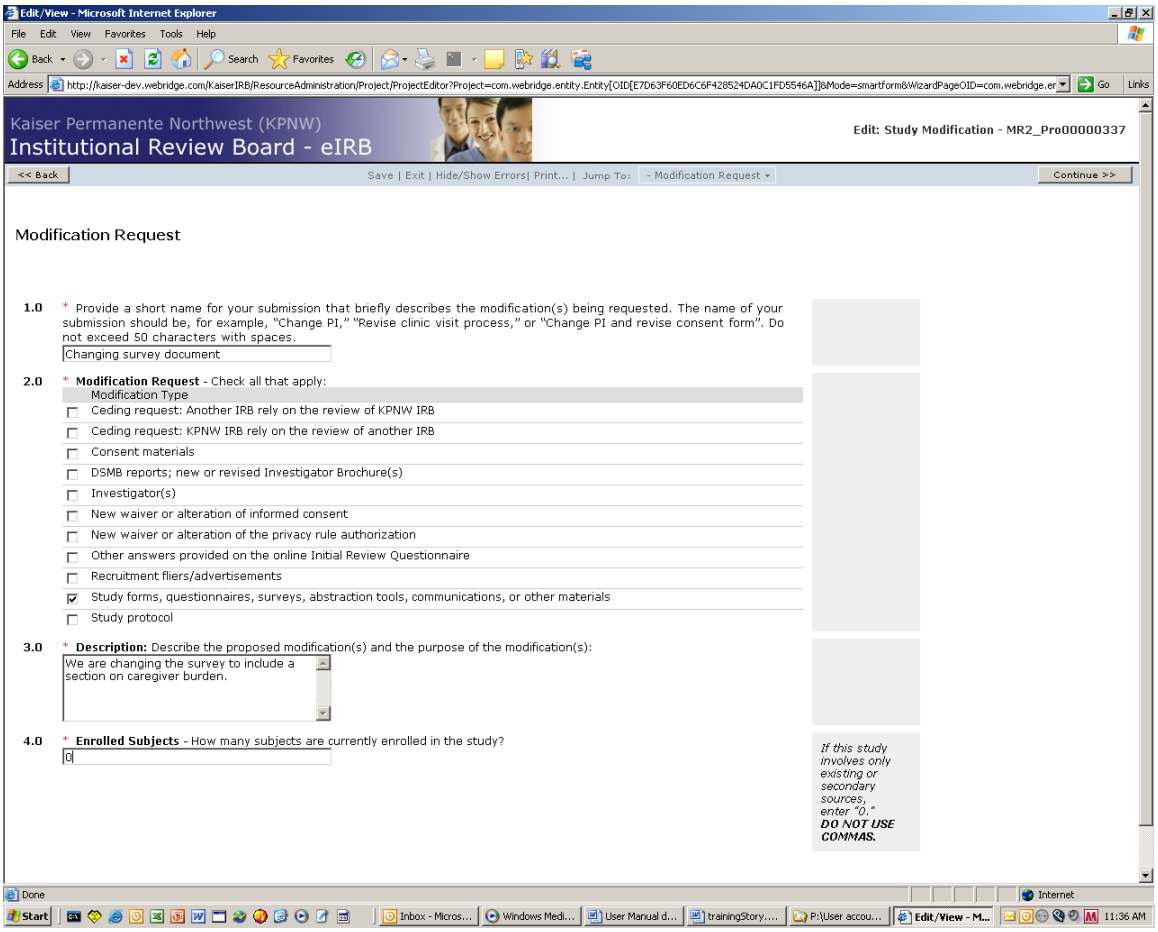
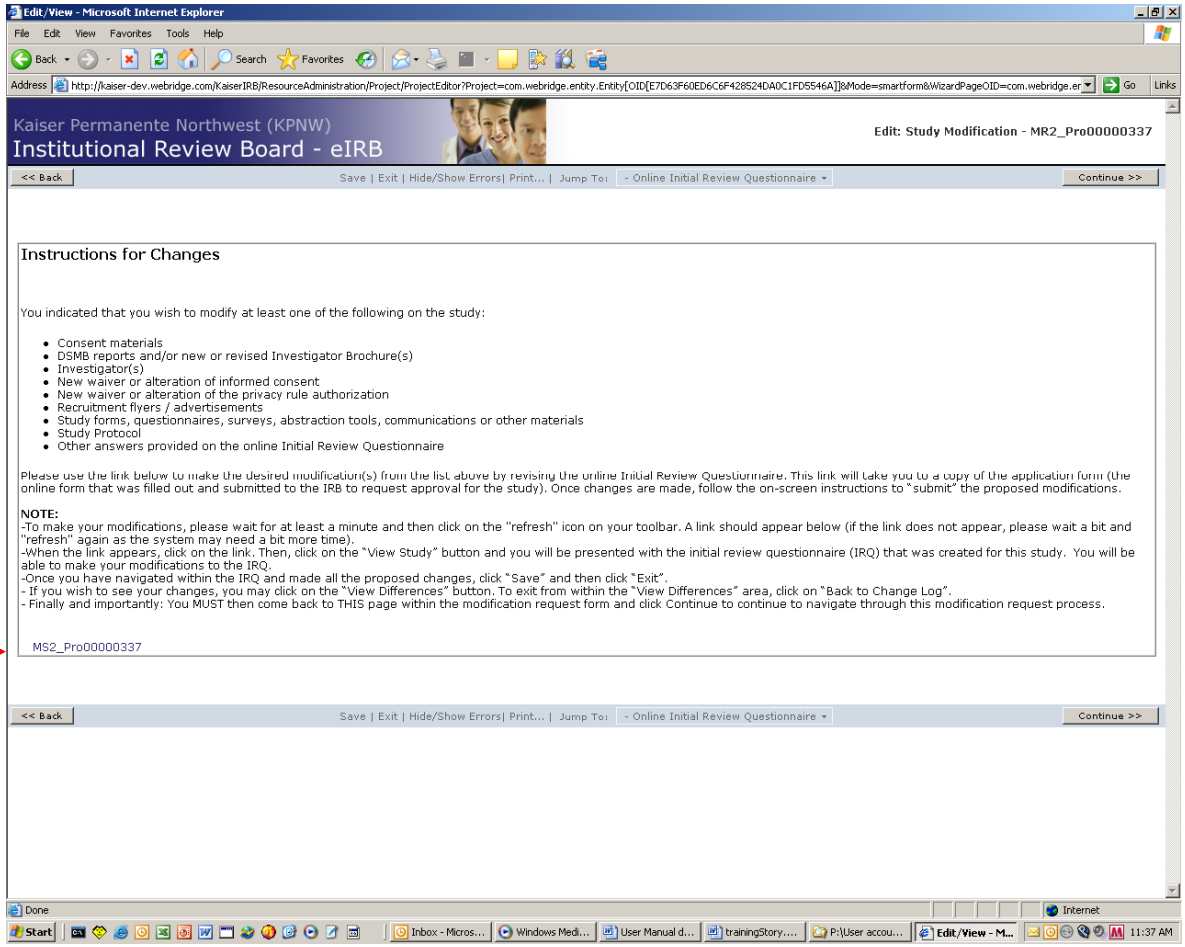

Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Edit: Study Modification - MR2_Pro00000337
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - Modification Request
Continue >>
Modification Request
1.0 * Provide a short name for your submission that briefly describes the modification(s) being requested. The name of your submission should be, for example, "Change PI," "Revise clinic visit process," or "Change PI and revise consent form". Do not exceed 50 characters with spaces.
Changing survey document
2.0 * Modification Request - Check all that apply:
Modification Type
Ceding request: Another IRB rely on the review of KPNW IRB
Ceding request: KPNW IRB rely on the review of another IRB
Consent materials
DSMB reports; new or revised Investigator Brochure(s)
Investigator(s)
New waiver or alteration of informed consent
New waiver or alteration of the privacy rule authorization
Other answers provided on the online Initial Review Questionnaire
Recruitment fliers/advertisements
Study forms, questionnaires, surveys, abstraction tools, communications, or other materials
Study protocol
3.0 * Description: Describe the proposed modification(s) and the purpose of the modification(s):
We are changing the survey to include a section on caregiver burden.
4.0 * Enrolled Subjects - How many subjects are currently enrolled in the study?
0
If this study involves only existing or secondary sources, enter "0." DO NOT USE COMMAS.

Figure 28

Once the first screen has been filled out, click on the "Continue" button in order to answer all applicable questions.

If your modification includes changes to any of the following, you will use a *link* to make the desired modification(s) by directly editing/revising a copy of the online-IRQ originally submitted.

- Consent materials
- DSMB reports and/or new or revised Investigator Brochure(s)
- Investigator(s)
- New waiver or alteration of informed consent
- New waiver or alteration of the privacy rule authorization
- Recruitment flyers/advertisements
- Study forms, questionnaires, surveys, abstraction tools, communications or other materials
- Study Protocol
- Other answers provided on the online Initial Review Questionnaire


Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Edit: Study Modification - MR2_Pro00000337
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - Online Initial Review Questionnaire
Continue >>
Instructions for Changes
You indicated that you wish to modify at least one of the following on the study:
Consent materials
DSMB reports and/or new or revised Investigator Brochure(s)
Investigator(s)
New waiver or alteration of informed consent
New waiver or alteration of the privacy rule authorization
Recruitment flyers / advertisements
Study forms, questionnaires, surveys, abstraction tools, communications or other materials
Study Protocol
Other answers provided on the online Initial Review Questionnaire
Please use the link below to make the desired modification(s) from the list above by revising the online Initial Review Questionnaire. This link will take you to a copy of the application form (the online form that was filled out and submitted to the IRB to request approval for the study). Once changes are made, follow the on-screen instructions to "submit" the proposed modifications.
NOTE:
-To make your modifications, please wait for at least a minute and then click on the "refresh" icon on your toolbar. A link should appear below (if the link does not appear, please wait a bit and "refresh" again as the system may need a bit more time).
-When the link appears, click on the link. Then, click on the "View Study" button and you will be presented with the initial review questionnaire (IRQ) that was created for this study. You will be able to make your modifications to the IRQ.
-Once you have navigated within the IRQ and made all the proposed changes, click "Save" and then click "Exit".
- If you wish to see your changes, you may click on the "View Differences" button. To exit from within the "View Differences" area, click on "Back to Change Log".
- Finally and importantly: You MUST then come back to THIS page within the modification request form and click Continue to continue to navigate through this modification request process.
MS2_Pro00000337
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - Online Initial Review Questionnaire
Continue >>
Done
Internet
Start
11:37 AM

link

Figure 29

The link shown in Figure 29 should appear after you hit "refresh" (as described in the instructions on screen); if the link does not appear, please wait a few minutes and then "refresh", as the system may need a bit more time. Click on the link shown in Figure 29. This will take you to an area where you can click on the "View Study" button (see Figure 30). This will present you with a *copy of the approved IRQ* (i.e., the online form that was filled out and submitted to the IRB to request approval for the study). You will be able to make your modifications directly onto this copy of the IRQ.

Use this same process to request to add documents and/or to edit/replace previously approved documents. To make the additions and/or the edits/replacements, navigate to the screen within the IRQ where such documents had been referred to/uploaded.

Once you have navigated within the IRQ and made all the proposed changes, click "Save" and then "Exit". Once the Study modification is complete and error-free, the PI should submit it for review using the "submit activity" (see submission section above).

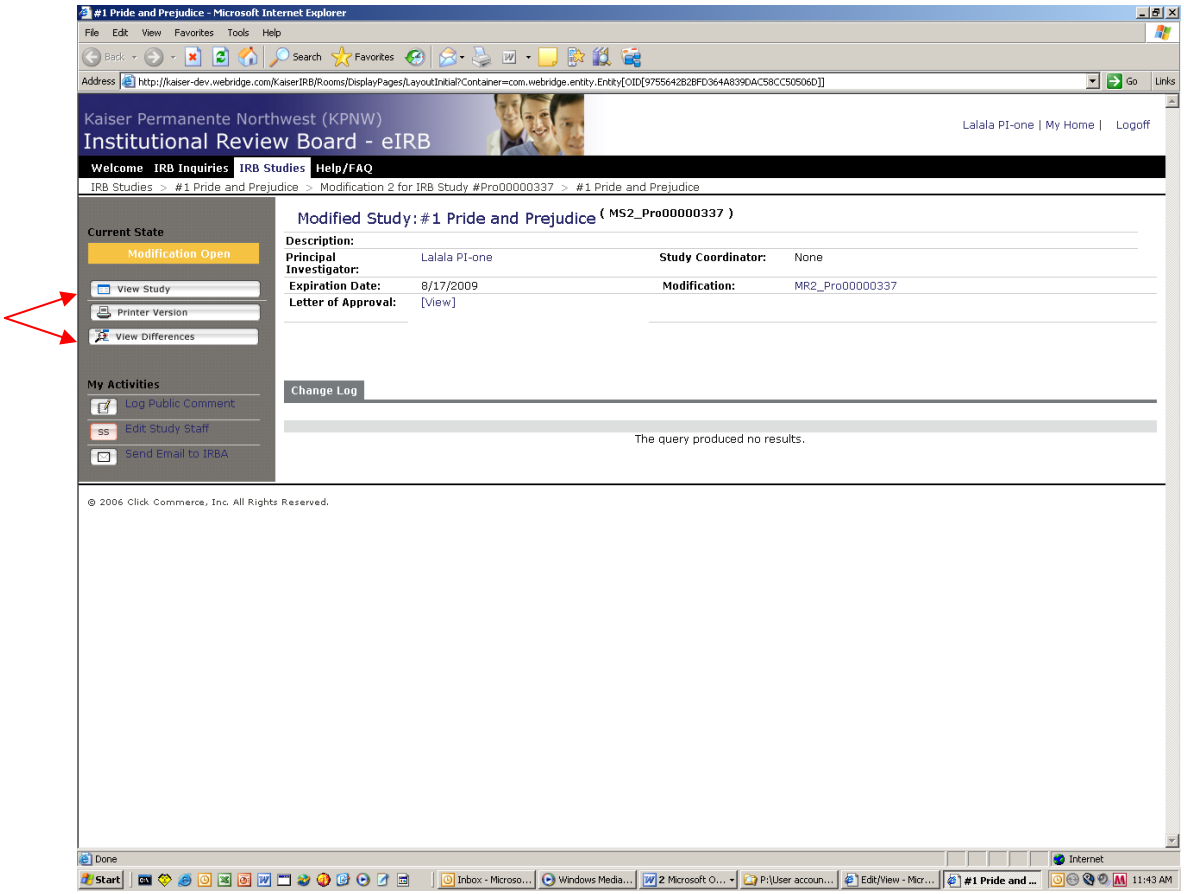

#1 Pride and Prejudice - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Lalala PI-one | My Home | Logoff
Welcome IRB Inquiries IRB Studies Help/FAQ
IRB Studies > #1 Pride and Prejudice > Modification 2 for IRB Study #Pro00000337 > #1 Pride and Prejudice
Current State
Modification Open
View Study
Printer Version
View Differences
My Activities
Log Public Comment
Edit Study Staff
Send Email to IRBA
Modified Study: #1 Pride and Prejudice (MS2_Pro00000337)
Description:
Principal Investigator: Lalala PI-one
Study Coordinator: None
Expiration Date: 8/17/2009
Modification: MR2_Pro00000337
Letter of Approval: [View]
Change Log
The query produced no results.
© 2006 Click Commerce, Inc. All Rights Reserved.

Figure 30

If you wish to see your requested changes to the IRQ compared to the approved version of the IRQ, you may click on the "View Differences" button (see Figure 30). Then, to exit the "View Differences" area, click on "Back to Change Log". Finally and importantly: You MUST then come back to the page within the modification request form (as shown in Figure 29) and click Continue to continue to navigate through this modification request. Then click "finish" on the final screen.

Investigator changes

Investigator changes, including INTERIM changes, need to happen via the Modification Request form. If a PI needs to have a co-investigator do submissions in their absence, the PI needs to submit a Modification Request to switch the PI name, and then another submission needs to be done later by the 'interim PI' to "switch it back".

To make modifications to 'converted hardcopy' studies

Because you were allowed to enter an abbreviated form to convert your hardcopy study, to make modifications to these 'converted' studies, you may need to use the question at the end of the IRQ which presents the following text-box labeled as follows: "Optional: If you feel there is important/relevant information about this research that was not solicited previously, provide this information below:". You can use this text box to write in information describing the proposed modifications.

You CAN do modifications/edits to documents (including adding new documents) on converted hardcopy studies since you were asked to upload documents with your conversion form. The documents you loaded are at the end of your IRQ. If you uploaded a protocol, you can also submit proposed modifications by tracking changes on your protocol document and submitting that for review.

An important note about modification requests

You may only initiate and be drafting one modification request at a time per study. Only one modification request can be 'submitted' (i.e., yet to be reviewed by the IRB) at a time. If you have already submitted a modification request to the IRB and realize you wish to request *another* modification *AND* if the modification request has *not* already been sent to a reviewer or discussed at an IRB meeting:

- You can contact the IRB (see Send Email to IRBA activity on the workspace) to ask if the already submitted modification request can be routed back to the investigator so that the investigator can insert/append the additional modification request(s) within the submission; *or*
- You may "withdraw" the original modification request submission. This would then allow the PI to create and submit an entirely new modification request.

If the RSPO has determined that a modification must go to the full board, but it is urgent that a minor modification be approved through an expedited review, the study may choose to withdraw the first modification request. The PI can submit the minor modifications, get the expedited approval for the minor modifications, and *then* submit the modification request that has to go to the full board.

CREATING REPORTABLE EVENT SUBMISSIONS

Reportable events are unanticipated events related to the research that involve increased risk to subjects.

In order to submit a Reportable Event, open your active study and click on the "New Reportable Event" button located in the left portion of the screen (see Figure 31). You are able to submit and have more than one Reportable Event submission pending IRB review at a time.

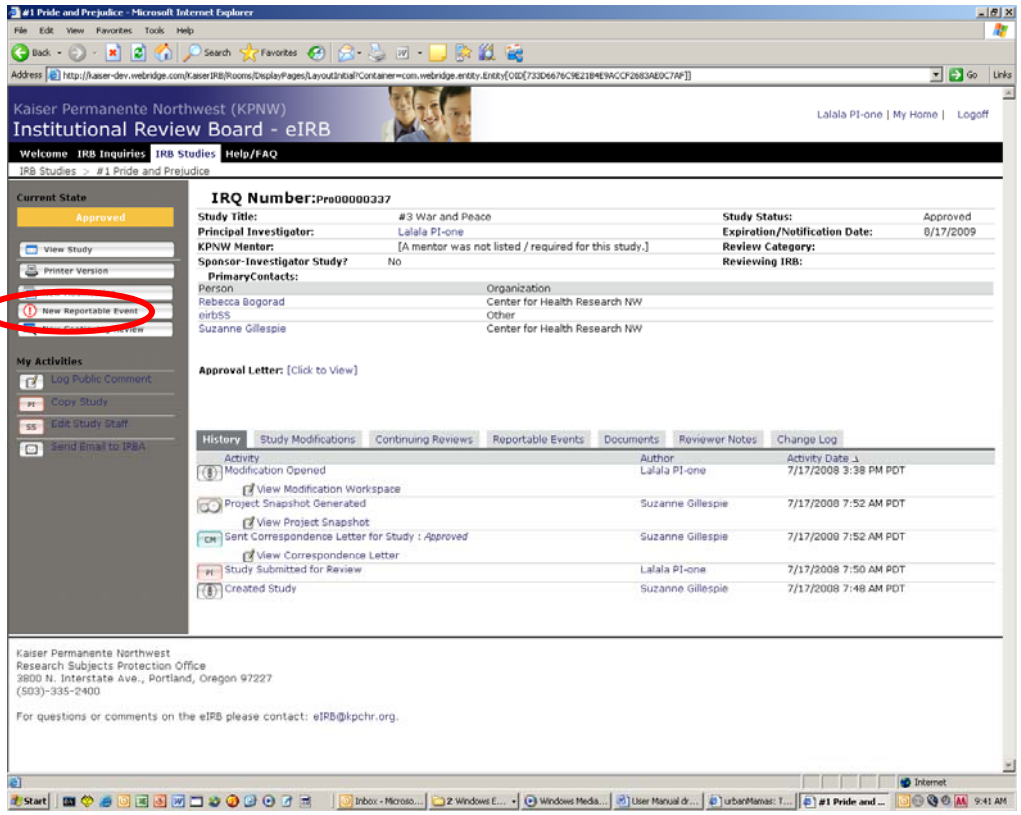


Figure 31

The Reportable Event form will open and prompt you to enter a short name for your submission. The name of the submission should be a short description of the event(s) being reported. For example, “Participant hospitalization”. Do not exceed 50 characters with spaces (see Figure 32).

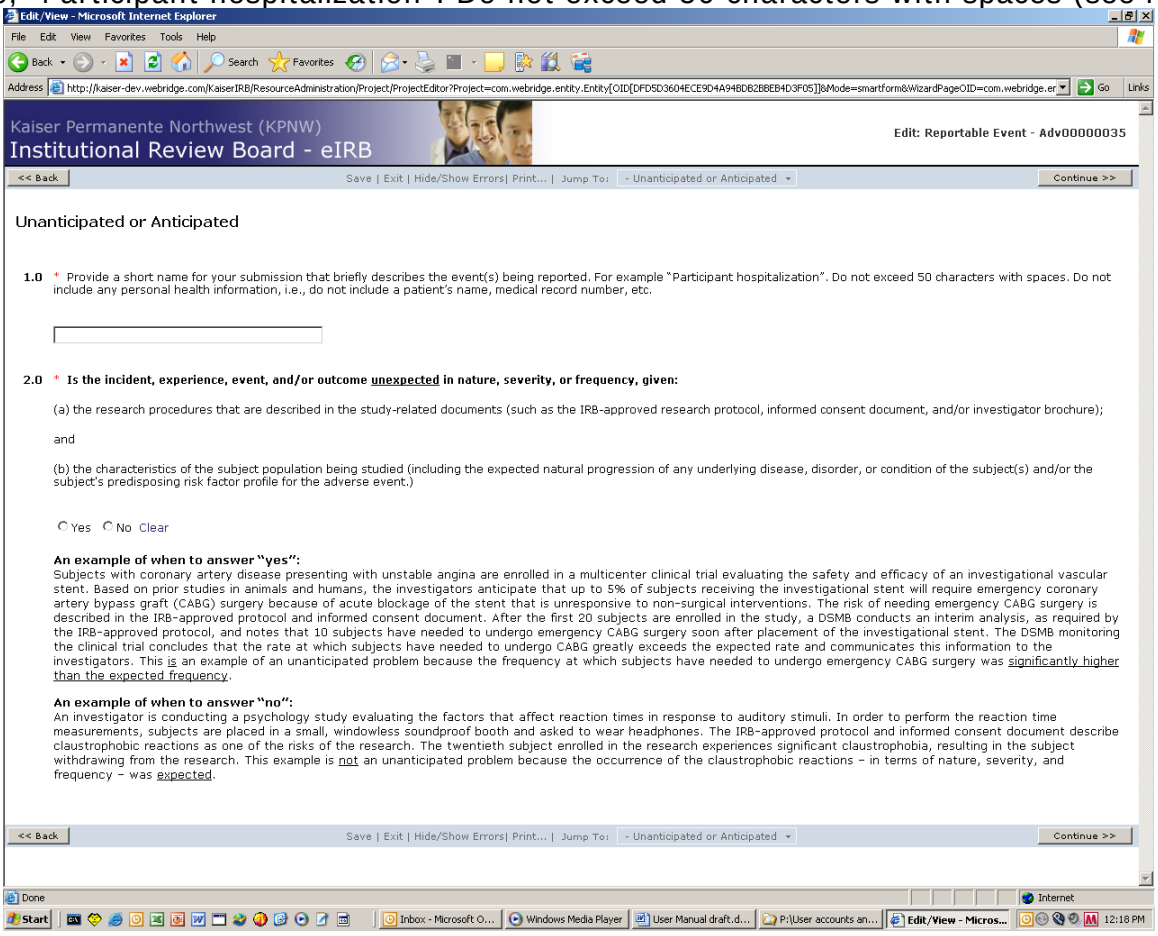

Edit/View - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Edit: Reportable Event - Adv00000035
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - Unanticipated or Anticipated
Continue >>
Unanticipated or Anticipated
1.0 * Provide a short name for your submission that briefly describes the event(s) being reported. For example "Participant hospitalization". Do not exceed 50 characters with spaces. Do not include any personal health information, i.e., do not include a patient's name, medical record number, etc.
2.0 * Is the incident, experience, event, and/or outcome unexpected in nature, severity, or frequency, given:
(a) the research procedures that are described in the study-related documents (such as the IRB-approved research protocol, informed consent document, and/or investigator brochure);
and
(b) the characteristics of the subject population being studied (including the expected natural progression of any underlying disease, disorder, or condition of the subject(s) and/or the subject's predisposing risk factor profile for the adverse event.)
Yes No Clear
An example of when to answer "yes":
Subjects with coronary artery disease presenting with unstable angina are enrolled in a multicenter clinical trial evaluating the safety and efficacy of an investigational vascular stent. Based on prior studies in animals and humans, the investigators anticipate that up to 5% of subjects receiving the investigational stent will require emergency coronary artery bypass graft (CABG) surgery because of acute blockage of the stent that is unresponsive to non-surgical interventions. The risk of needing emergency CABG surgery is described in the IRB-approved protocol and informed consent document. After the first 20 subjects are enrolled in the study, a DSMB conducts an interim analysis, as required by the IRB-approved protocol, and notes that 10 subjects have needed to undergo emergency CABG surgery soon after placement of the investigational stent. The DSMB monitoring the clinical trial concludes that the rate at which subjects have needed to undergo CABG greatly exceeds the expected rate and communicates this information to the investigators. This is an example of an unanticipated problem because the frequency at which subjects have needed to undergo emergency CABG surgery was significantly higher than the expected frequency.
An example of when to answer "no":
An investigator is conducting a psychology study evaluating the factors that affect reaction times in response to auditory stimuli. In order to perform the reaction time measurements, subjects are placed in a small, windowless soundproof booth and asked to wear headphones. The IRB-approved protocol and informed consent document describe claustrophobic reactions as one of the risks of the research. The twentieth subject enrolled in the research experiences significant claustrophobia, resulting in the subject withdrawing from the research. This example is not an unanticipated problem because the occurrence of the claustrophobic reactions – in terms of nature, severity, and frequency – was expected.
<< Back
Save | Exit | Hide/Show Errors| Print... | Jump To: - Unanticipated or Anticipated
Continue >>
Done
Internet
Start
Inbox - Microsoft O...
Windows Media Player
User Manual draft.d...
P:\User accounts an...
Edit/View - Micros...
12:18 PM

Figure 32

Answer the next question and click on the “Continue” button in order to navigate through the questionnaire while answering all relevant questions. On the last page of the reportable event form, click “finish” to complete the questionnaire. Once the form is complete and error-free the PI should submit it for review using the “submit activity” (see submission section above).

You may discover that the event is NOT required to be reported to the IRB, or that it should only be reported in summary at the time of continuing review. The eIRB system will ascertain, through a series of questions, whether the event must be reported. You will be guided to submit, or to simply ‘exit’ and not submit.

Generally, studies will use this Reportable Event form to report problematic unanticipated incidents, experiences, events, and outcomes related to the study that have resulted in subjects or others experiencing physical, psychological, or other harms (such as social or economic harm) or that place subjects or others at increased risk of harm. In addition to this general rule, FDA-regulated studies with a KPNW sponsor-investigator (only) would *also* use this form to report any other additional incidents, experiences, events, and outcomes as were specifically stipulated and required by the KPNW IRB for the study.

CREATING IRB INQUIRIES

There is a new, optional submission type that was not available prior to the eIRB system. The form is designed for situations in which there is uncertainty about whether IRB review is necessary for a new project. This *optional* inquiry form would be submitted *prior* to a new study submission if you are unsure whether IRB review is required. When this form is submitted, it will be sent to a reviewer who will then indicate whether the new project will require IRB review.

In order to submit an inquiry form, from your home page click on the "New IRB Inquiry" button located in the left portion of the screen (see Figure 33). This will bring up a short, one-page form (see Figure 34).

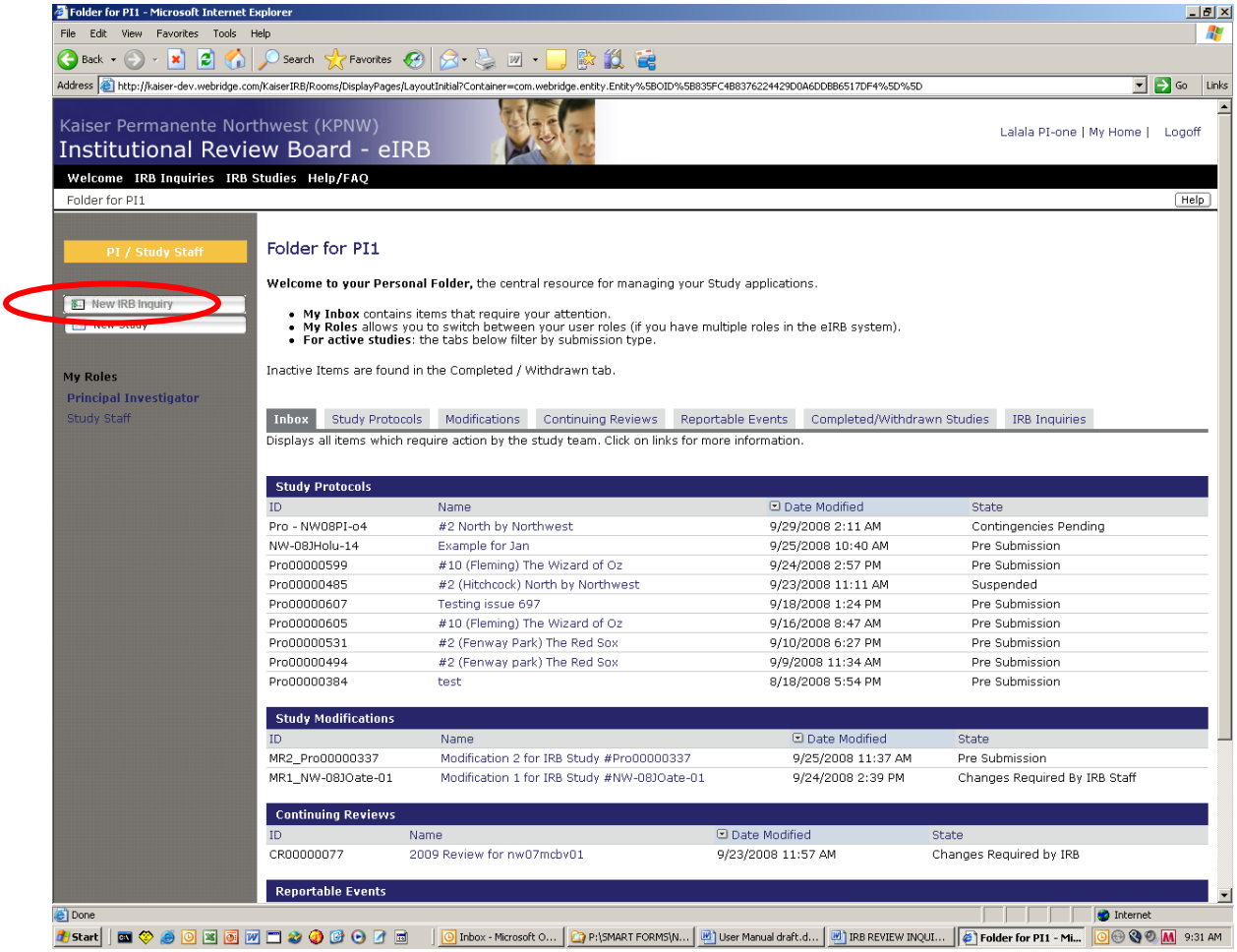

Folder for PI1 - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Lalala PI-one | My Home | Logoff
Welcome IRB Inquiries IRB Studies Help/FAQ
Folder for PI1
Help
PI / Study Staff
New IRB Inquiry
My Roles
Principal Investigator
Study Staff
Folder for PI1
Welcome to your Personal Folder, the central resource for managing your Study applications.
My Inbox contains items that require your attention.
My Roles allows you to switch between your user roles (if you have multiple roles in the eIRB system).
For active studies: the tabs below filter by submission type.
Inactive Items are found in the Completed / Withdrawn tab.
Inbox
Study Protocols
Modifications
Continuing Reviews
Reportable Events
Completed/Withdrawn Studies
IRB Inquiries
Displays all items which require action by the study team. Click on links for more information.
Study Protocols
ID Name Date Modified State
Pro - NW08PI-04 #2 North by Northwest 9/29/2008 2:11 AM Contingencies Pending
NW-08JHolu-14 Example for Jan 9/25/2008 10:40 AM Pre Submission
Pro00000599 #10 (Fleming) The Wizard of Oz 9/24/2008 2:57 PM Pre Submission
Pro00000485 #2 (Hitchcock) North by Northwest 9/23/2008 11:11 AM Suspended
Pro00000607 Testing issue 697 9/18/2008 1:24 PM Pre Submission
Pro00000605 #10 (Fleming) The Wizard of Oz 9/16/2008 8:47 AM Pre Submission
Pro00000531 #2 (Fenway Park) The Red Sox 9/10/2008 6:27 PM Pre Submission
Pro00000494 #2 (Fenway park) The Red Sox 9/9/2008 11:34 AM Pre Submission
Pro00000384 test 8/18/2008 5:54 PM Pre Submission
Study Modifications
ID Name Date Modified State
MR2_Pro00000337 Modification 2 for IRB Study #Pro00000337 9/25/2008 11:37 AM Pre Submission
MR1_NW-08JOate-01 Modification 1 for IRB Study #NW-08JOate-01 9/24/2008 2:39 PM Changes Required By IRB Staff
Continuing Reviews
ID Name Date Modified State
CR00000077 2009 Review for nw07mcbv01 9/23/2008 11:57 AM Changes Required by IRB
Reportable Events

Figure 33

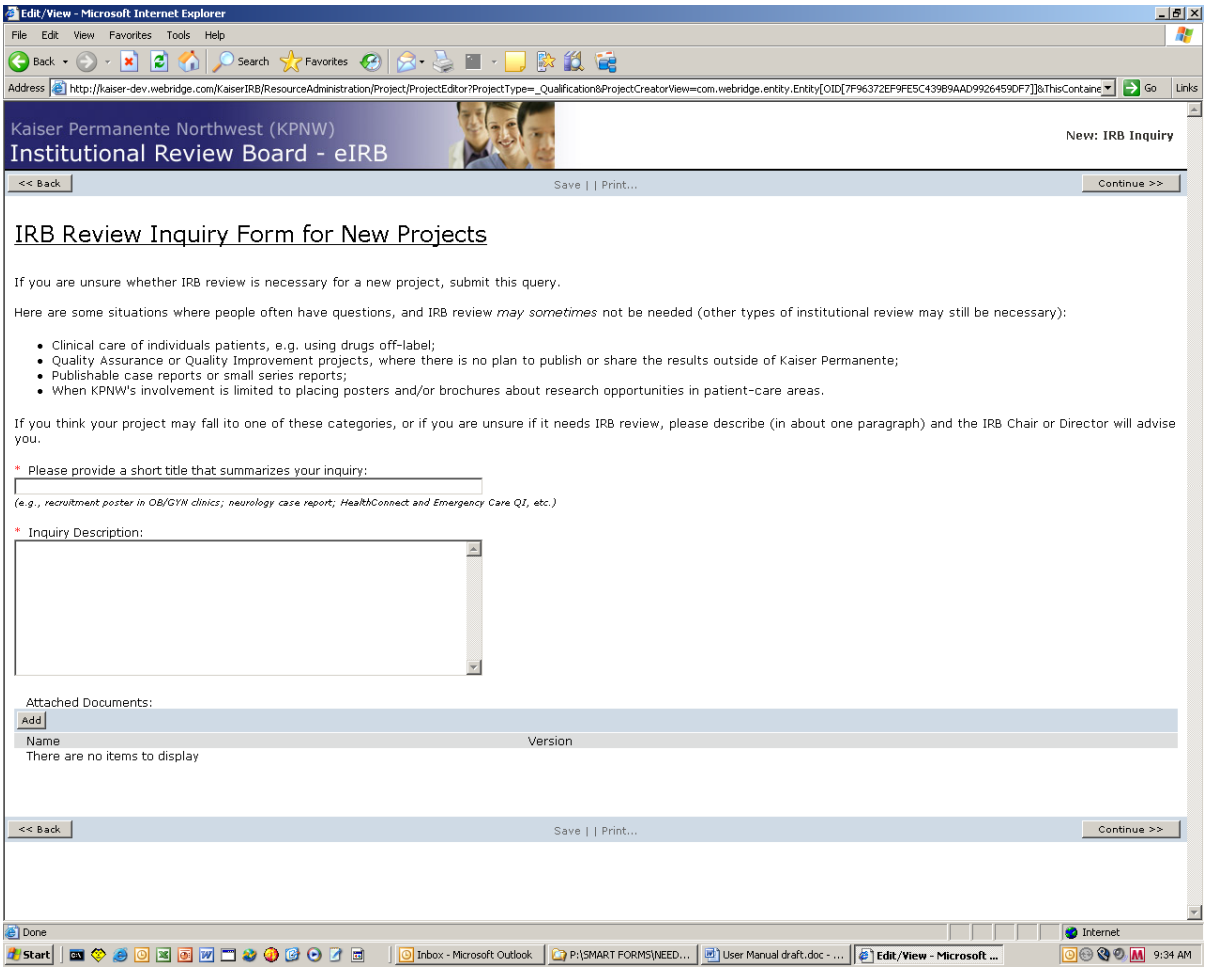

Edit/View - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://kaiser-dev.webridge.com/KaiserIRB/ResourceAdministration/Project/ProjectEditor?ProjectType=_Qualification&ProjectCreatorView=com.webridge.entity.Entity[OID[7F96372EF9FE5C439B9AAD9926459DF7]]&ThisContaine
Go Links
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
New: IRB Inquiry
<< Back
Save | | Print...
Continue >>
IRB Review Inquiry Form for New Projects
If you are unsure whether IRB review is necessary for a new project, submit this query.
Here are some situations where people often have questions, and IRB review may sometimes not be needed (other types of institutional review may still be necessary):
Clinical care of individuals patients, e.g. using drugs off-label;
Quality Assurance or Quality Improvement projects, where there is no plan to publish or share the results outside of Kaiser Permanente;
Publishable case reports or small series reports;
When KPNW's involvement is limited to placing posters and/or brochures about research opportunities in patient-care areas.
If you think your project may fall ito one of these categories, or if you are unsure if it needs IRB review, please describe (in about one paragraph) and the IRB Chair or Director will advise you.
* Please provide a short title that summarizes your inquiry:
(e.g., recruitment poster in OB/GYN clinics; neurology case report; HealthConnect and Emergency Care QI, etc.)
* Inquiry Description:
Attached Documents:
Add
Name
Version
There are no items to display
<< Back
Save | | Print...
Continue >>
Done
Internet
Start
Inbox - Microsoft Outlook
P:\SMART FORMS\NEED...
User Manual draft.doc - ...
Edit/View - Microsoft ...
9:34 AM

Figure 34

GLOSSARY: UNDERSTANDING "ACTIVITIES"

(See Figure 22)

Accept Cede from other IRB – ALLOWS RSPO to indicate that the KPNW IRB accepts review responsibility for another IRB.

Acknowledge – ALLOWS RSPO to acknowledge receipt of reportable event submission.

Agree to mentor – ALLOWS the Mentor to attest to their mentoring responsibilities on the study, if a mentor is needed on the study.

Ceding revoked – ALLOWS the RSPO staff to revoke "ceded status" on an active study, indicating that the KPNW IRB will assume review of the study.

Changes requested by contingency reviewer - ALLOWS the RSPO to forward a request for changes to the PI.

Changes Required by Expedited Reviewer – ALLOWS the RSPO to forward a request for changes to the PI.

Changes Required by IRB Staff – ALLOWS RSPO to submit a change request to the PI; the Principal Investigator will be notified that changes are required to the protocol.

Continuing review completed – ALLOWS RSPO to indicate that a continuing review is now complete. The study will therefore be in an 'approved' state.

Copy Study - This activity will COPY this study. The same Principal investigator will remain the Principal Investigator for the new Study.

Deny Cede from Other IRB - ALLOWS RSPO to indicate that the KPNW IRB does not accept review responsibility for another IRB.

Edit Consent Forms – Allows RSPO staff to modify the contents of the set of draft consent forms prior to project approval and document watermarking. Documents added to the draft consent form set via this activity will be available for watermarking using the Finalize Documents activity.

Edit Guest List – ALLOWS any member of the study team to edit (i.e., add, delete) the primary and secondary study staff/contacts on the project. (Does NOT allow either PI or co-investigator edits, which must be made through a modification request).

Edit letter- Allows RSPO staff to modify a letter that was previously sent to the study team (in the instance of an error or other need to revise).

Expedite approval – ALLOWS IRB Director to expedite approval of a submission.

Final Report Completed – ALLOWS the RSPO staff to indicate that a ceded study is closed.

Finalize Documents – ALLOWS RSPO staff to stamp and watermark multiple draft consent forms with the project approval and expiration dates. Once finalized, a copy of the corresponding document in the set of draft consent forms is converted to a read-only PDF, and is placed in the set of Approved Consent Forms for this project.

Issue Mentor Approval - ALLOWS the Mentor to approve a modification request submission.

Log Public Comment -ALLOWS any member of the study team or the IRB staff to log a comment in the project history log that is visible to everyone that has read access to the project. See Figure 35.

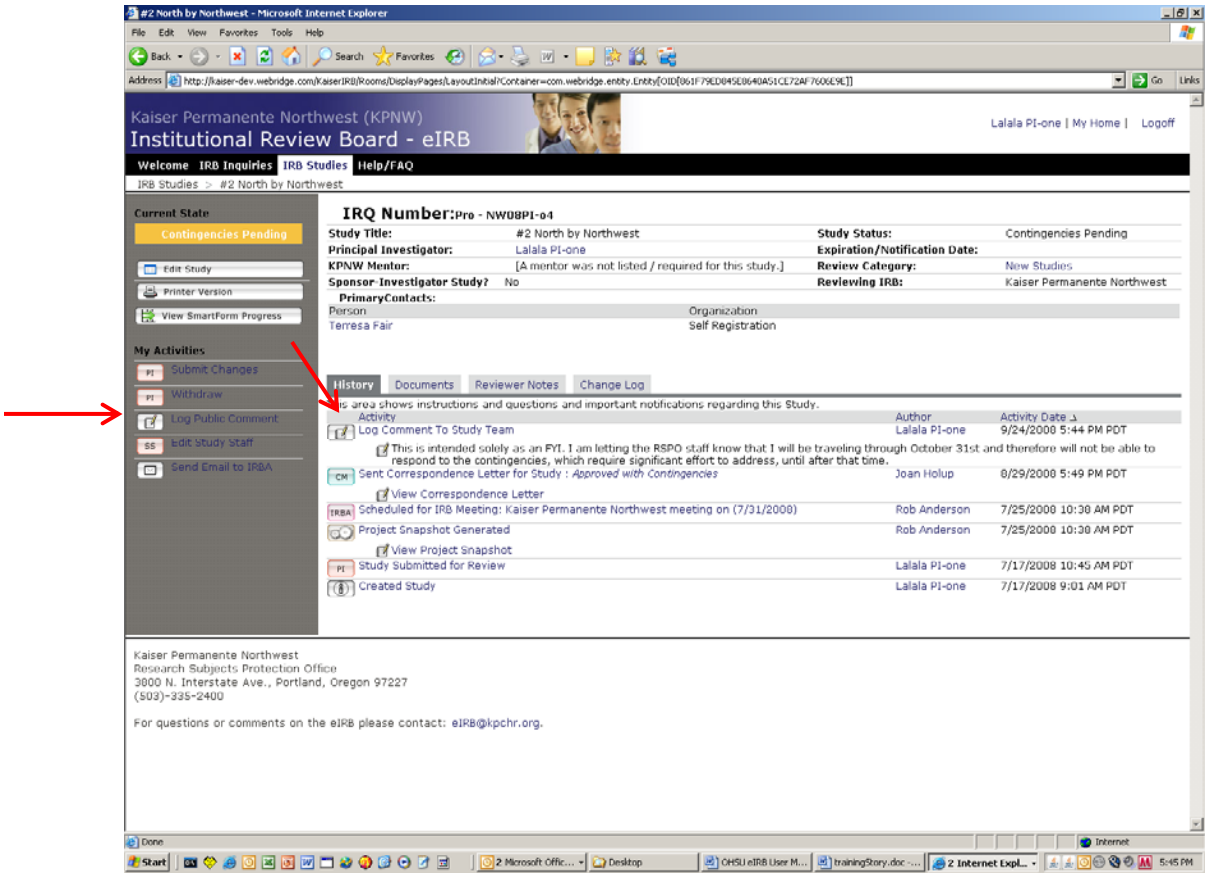

#2 North by Northwest - Microsoft Internet Explorer
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
Lalala PI-one | My Home | Logoff
Welcome IRB Inquiries IRB Studies Help/FAQ
IRB Studies > #2 North by Northwest
Current State
Contingencies Pending
Edit Study
Printer Version
View SmartForm Progress
My Activities
Submit Changes
Withdraw
Log Public Comment
Edit Study Staff
Send Email to IRBA
IRQ Number:Pro - NW08PI-04
Study Title: #2 North by Northwest
Study Status: Contingencies Pending
Principal Investigator: Lalala PI-one
Expiration/Notification Date:
KPNW Mentor: [A mentor was not listed / required for this study.]
Review Category: New Studies
Sponsor-Investigator Study? No
Reviewing IRB: Kaiser Permanente Northwest
PrimaryContacts:
Person
Organization
Terresa Fair
Self Registration
History
Documents
Reviewer Notes
Change Log
Activity
Author
Activity Date
Log Comment To Study Team
Lalala PI-one
9/24/2008 5:44 PM PDT
This is intended solely as an FYI. I am letting the RSPO staff know that I will be traveling through October 31st and therefore will not be able to respond to the contingencies, which require significant effort to address, until after that time.
Sent Correspondence Letter for Study : Approved with Contingencies
Joan Holup
8/29/2008 5:49 PM PDT
View Correspondence Letter
Scheduled for IRB Meeting: Kaiser Permanente Northwest meeting on (7/31/2008)
Rob Anderson
7/25/2008 10:30 AM PDT
Project Snapshot Generated
Rob Anderson
7/25/2008 10:30 AM PDT
View Project Snapshot
Study Submitted for Review
Lalala PI-one
7/17/2008 10:45 AM PDT
Created Study
Lalala PI-one
7/17/2008 9:01 AM PDT
Kaiser Permanente Northwest
Research Subjects Protection Office
3000 N. Interstate Ave., Portland, Oregon 97227
(503)-335-2400
For questions or comments on the eIRB please contact: eIRB@kpchr.org.

Figure 35

Other IRB accepts reliance and documents complete– ALLOWS the RSPO to indicate in the system that the other IRB has accepted review responsibility for the KPNW IRB. The study will be considered "ceded" upon execution of this activity.

Other IRB denies request– ALLOWS the RSPO to indicate in the system that the other IRB does not accept review responsibility for the KPNW IRB. The submission reverts to 'pre-submission' status.

Reactivate – ALLOWS PI/SS to reactive the submission, which was previously 'withdrawn', so it can then be worked with/submitted.

Revoke Verification - ALLOWS the RSPO to indicate that a study previously verified as 'exempt' from IRB review now requires IRB review.

Schedule for IRB Meeting – ALLOWS RSPO to place the submission on a Board agenda and to assign a primary reviewer.

Send Correspondence to Study Team - ALLOWS correspondence manager to send IRB Correspondence to the study team.

Send email to IRBA - ALLOWS the study team to email the RSPO within the eIRB environment.

Study Completed – ALLOWS the study team to indicate that an exempt study is closed.

Submit – Once the submission draft is 'finished', 'Submit' ALLOWS the form to be submitted for IRB review. Reminder: The PI is the only person that can *submit*.

Submit Changes – ALLOWS the Principal Investigator to respond to a request for changes or clarifications from the IRB staff

Submit changes or contingency response – ALLOWS the PI to submit the requested changes or response to contingencies. Reminder: The PI is the only person that can *submit*.

Submit Continuing Review – Once the submission draft is 'finished', ALLOWS the PI to submit the form for IRB review. Reminder: The PI is the only person that can *submit* submissions.

Submit study – If you are the PI for a study, only you will have the option to submit (equivalent to a signature on paper) the study, continuing review, reportable event, or modification request. Once you have opened the submission draft and have reviewed it for accuracy, you may click on the "Submit" activity located on the left section of the submission workspace page under My Activities. Once the submit action has been completed, the submission will enter the review process.

Suspend study– ALLOWS the PI or IRB to suspend a study; suspended studies must temporarily cease all study activities except those required to protect the health and welfare of study participants.

Terminate study– ALLOWS the PI or IRB to terminate a study, after which the study will no longer be in an 'IRB-approved' status.

Withdraw – ALLOWS the item to be withdrawn and archived. The "Withdraw" action allows the PI to effectively cancel the submission. This action will be useful if, during the review process, events impact the plans for the study and it is decided that the study or particular submission will not proceed. Withdrawing the study will not delete the study and its information, but rather archive it. You will still be able to retrieve the information you have entered into the IRQ should the need arise in the future. See Figures 36 and 37.

To withdraw a study, click 'withdraw'.

This form will then pop-up so that you can indicate a general reason for withdrawing and include any comments.

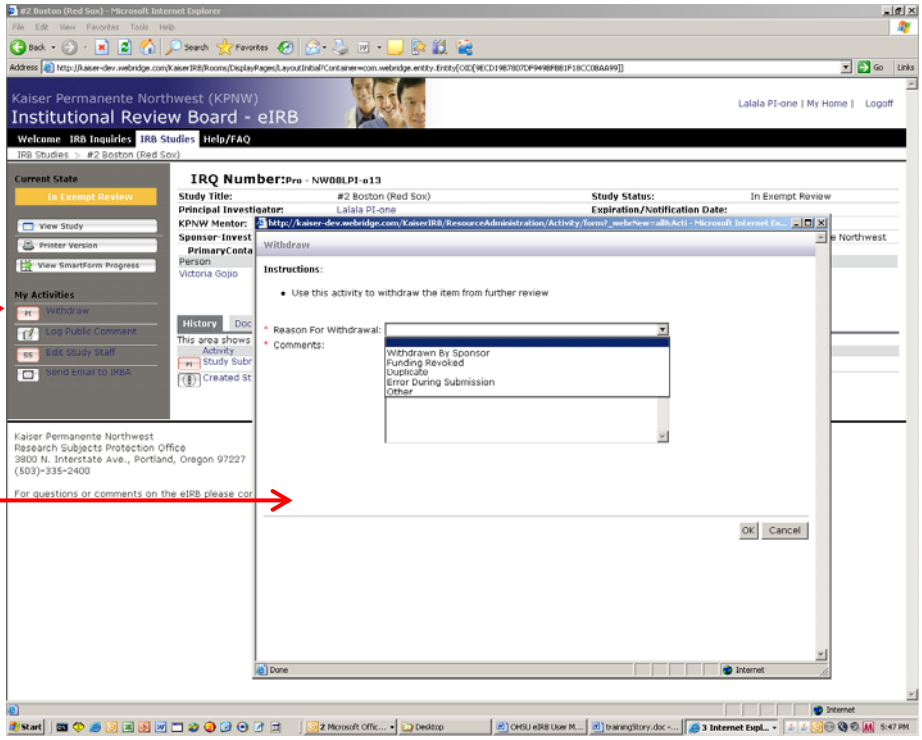


Figure 36

The study will then be in a 'withdrawn' state. If you wish to submit it later, you 'Reactivate' the submission, which will put it in a 'Pre-submission' state for you to revise, if needed, and then 'submit' again for review.

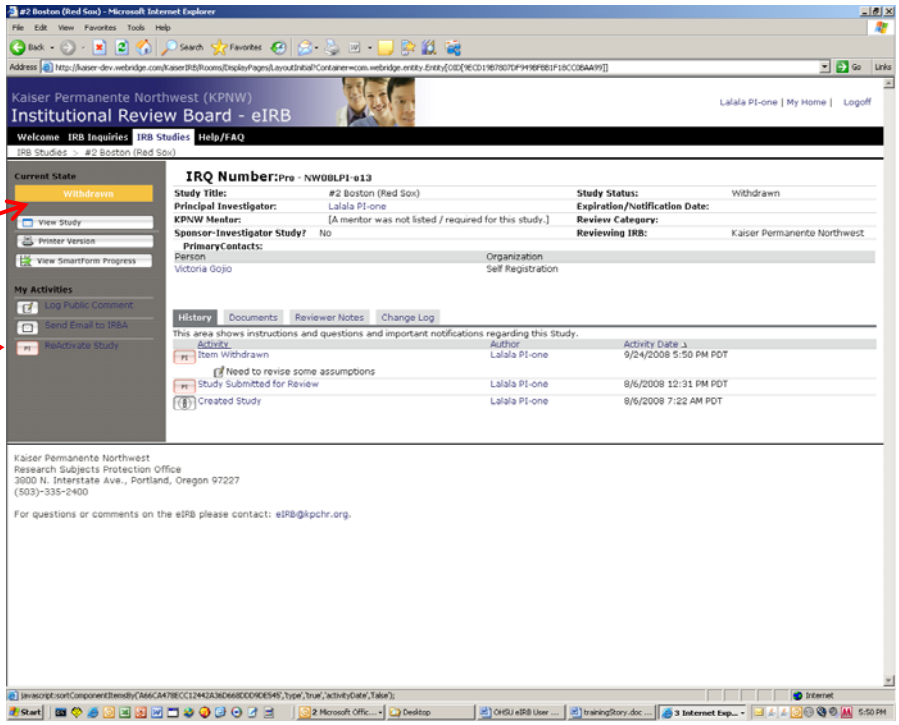


Figure 37

GLOSSARY: UNDERSTANDING "CURRENT STATES"

(See Figure 22)

There are many different submission states. The following definitions (sorted in alphabetical order) provide a comprehensive explanation.

Acknowledged– The Reportable Event submission has been acknowledged.
Approved – The study, or submission, has been approved.
Assigned to IRB Meeting – The submission has been assigned to a KPNW IRB meeting.
Awaiting Correspondence - The submission has been reviewed. The RSPO is preparing related correspondence that will be sent to the study team.
Awaiting Other IRB Acceptance of Review - The ceding /reliance request submitted by the study team has been reviewed by the KPNW IRB. The KPNW IRB has contingently approved the request and is waiting for communication from the other IRB about whether they agree to accept the review responsibility.
Ceded to Other IRB - The ceding /reliance request submitted by the study team has been reviewed by the KPNW IRB. The KPNW IRB approved the request and the other IRB agreed to accept the review responsibility. The KPNW IRB is now relying on another IRB to conduct review of the study (it is 'ceded').
Changes Required by Exempt Reviewer - The submission has been forwarded to an exempt reviewer. The exempt reviewer has requested changes / clarifications from the PI.
Changes Required by Expedited Reviewer - The submission has been forwarded to an expedited reviewer. The expedited reviewer has requested changes / clarifications from the PI.
Changes Required by IRB – The IRB has reviewed the submission and has requested changes / clarifications from the PI.
Changes Required by IRB Staff – The IRB/RSPO staff have requested changes / clarifications from the PI.
Committee Member Review - The submission has been forwarded to a reviewer.
Changes Required by Committee Member Review (RE) - The Reportable Event submission has been forwarded to a reviewer. The reviewer has requested changes / clarifications from the PI.
Complete - The study is complete / closed/ no longer active.
Contingencies Pending - The IRB has reviewed the submission and has approved the submission 'with contingencies'. A response is now required from the PI in order for the submission to be formally approved.
Correspondence Review - The submission has been reviewed. The RSPO is preparing related correspondence that will be sent to the study team.
Designated Reviewer Contingency Review - The submission was reviewed and approved 'with contingencies'. The PI submitted a response, and this response is under review. (The PI response must be reviewed in order for the submission to be formally approved).
Disapproved– The study, or submission, was disapproved by the IRB.
Exempt Verified - The study was determined to be exempt from IRB review.
Expired - The study's IRB approval has expired.

In Exempt Review - The study has been forwarded to reviewer who will determine if the study is 'exempt' from IRB review.

In Expedited Review - The submission has been forwarded to a reviewer who will determine if the submission qualifies for expedited review.

In Expedited Review Contingencies Review - The submission was forwarded to a reviewer to determine if the submission qualifies for expedited review. The reviewer has requested changes/clarifications from the PI. A response is now required from the PI in order for the submission to be formally approved.

In Expedited Review Staff Review - The submission was forwarded to a reviewer to determine if the submission qualifies for expedited review. The submission is now with the RSPO.

IRB Correspondence Review - The submission has been reviewed. The RSPO is preparing related correspondence that will be sent to the study team.

IRB Qualification Review (inquiry) - The IRB Inquiry has been forwarded to a reviewer who will determine if the project will require IRB review.

IRB Staff Contingency Review - The submission was reviewed and approved 'with contingencies'. The submission is now with the RSPO.

IRB Staff Review - The submission is now with the RSPO to administratively handle.

Meeting Complete Awaiting Correspondence - The submission has been reviewed at an IRB meeting. The RSPO is preparing related correspondence that will be sent to the study team.

Pre Submission - The submission is being prepared by the study team.

Qualification Review Complete (inquiry) - The IRB Inquiry was reviewed and is complete.

Suspended - The study's IRB approval is 'suspended'.

Terminated – The study's IRB approval has been "terminated".

Withdrawn - The submission was withdrawn from the review process. It is no longer active within the review process.

GETTING HELP

eIRB Technical Support

You may receive technical assistance for the Kaiser Permanente Northwest (KPNW) eIRB system by contacting eIRB technical support at 503-528-3945 (tieline 60 3945) or at eIRB@kpchr.org during the following hours:

Monday - Friday ..... 9AM – 4:00PM

You may also request an eIRB Training Session. Information regarding training can be found on the eIRB main page at http://eIRB.kpchr.org.

Study (IRB) Related Support

For questions related to the wording and the meaning of the questions found within the eIRB, feel free to contact the Research Subjects Protections Office (RSPO) at (503) 335-6699 or at RSPO@kpchr.org.

You can also view the list of RSPO personnel and their contact information at http://www.kpchr.org/rspopublic/public/contactus.aspx?returnurl=/rspopublic/public/default.aspx&siteid=1.

Additionally, RSPO maintains a web site with useful information at http://www.kpchr.org/rspopublic/public/.

General Computer Help Desk

The General Computer Help Desk provided by the Center for Health Research/KPNW can be reached at 503-335-6671 (tie line 60-6671) or at hotline@kpchr.org for questions that are *not* related to the eIRB, such as questions relating to your operating system, network access, and common software applications installed on your computer.

Browser Requirements

Microsoft® Windows 9x, 2000, XP

- Microsoft® Internet Explorer 6.0 or higher available at http://www.microsoft.com/windows/ie/default.mspx

- Firefox 1.0 or higher on Windows platforms available at http://www.mozilla.com/en-US/products/firefox/

System Requirements

The eIRB system will function on Microsoft® Windows 95 and higher as long as the computer has Microsoft® Internet Explorer 6.0 or higher with cipher strength of 128 bit installed.

EXAMPLES OF COMMON ERROR MESSAGES

- You may experience the following error if the system is undergoing maintenance or service:

  "An internal server error occurred. We apologize for the inconvenience, and ask that you please try again later. If you continue to experience problems please contact the eIRB help desk at 503-528-3945 or eIRB@kpchr.org."

- You may be presented with the following message if the eIRB system is *already* in the process of uploading a file into your submission and you attempt to upload a file again:

  "You have already submitted the current form. Please wait and the operation will be completed momentarily."

- The following messages indicate that you have omitted to answer a required question on a screen:

  "Could not update the IRQ due to one or more errors:
  There were problems submitting this form..."

  This is a required field; therefore, you must provide a value.

- Example of error message generated if there is incongruous information entered, for example, if the numbered entered for 'total' study subjects is less than the numbered entered for study subjects 'specifically enrolled at the KPNW site':

  "Could not update the Continuing Review due to one or more errors:
  Validation Failed: The number entered for Newly Enrolled is greater than the Current Number of Participants/Subjects in the Study (at this site). You must revise your number(s)."

WHAT IS NOT FOUND IN THE E-IRB

- Single-patient use submission forms

- Emergency-use submission forms

If you need to make one of these types of submission to the KPNW IRB, please contact the RSPO for guidance.